(a) DS292 (Canada)

7.2524 Canada has stated that if the Panel determines that parts of the relevant product-specific measures are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's claims under the *TBT Agreement* are to be considered cumulative rather than alternative. We note that each of the four product-specific measures challenged by Canada concerns an approval procedure which was conducted under Directive 90/220. In two cases, the relevant procedure was continued under Directive 2001/18 after the repeal of Directive 90/220. We have found that the relevant approval procedures set out in these Directives are SPS measures within the meaning of Annex A(1) of the *SPS Agreement*. We did not determine that parts of the approval procedures set out in the Directives are not covered by the *SPS Agreement*. In the light of this, and in view of Article 1.5 of the *TBT Agreement*[1670], we have no basis for finding that parts of the relevant approval procedures are covered by the *TBT Agreement* in addition to the *SPS Agreement*. Consequently, we should treat Canada's claims under Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement* as alternative claims. Since Canada's alternative claims are relevant only in the event that we decide that the relevant product-specific measures are not subject to the *SPS Agreement*, and since we have found that these measures are subject to the *SPS Agreement* (notably Annex C(1)(a) and Article 8), we see no need to address Canada's alternative claims under Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement* further.

(b) DS293 (Argentina)

7.2525 Argentina's claim that the product-specific measures it is challenging are inconsistent with the *TBT Agreement* is presented in the alternative, in the event the Panel "considers that it should not analyse Argentina's claim under the *SPS Agreement*".[1671]

7.2526 Regarding the product-specific measures described by Argentina as the undue delays in finalizing consideration of particular applications, we found above that the European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and Article 8 of the *SPS Agreement* in respect of each of the eight measures concerned. Accordingly, in respect of these measures, we found that we *should* analyse Argentina's claim under the *SPS Agreement*. Since Argentina's alternative claim under the *TBT Agreement* is relevant only in the event that we consider that the relevant product-specific measures should *not* be analysed under the *SPS Agreement*, we see no need to address Argentina's alternative claim under the *TBT Agreement* further.

7.2527 Regarding the product-specific measures described by Argentina as the suspension by the European Communities of consideration of, or the failure to consider, particular applications, we found above that Argentina has not established that the European Communities acted inconsistently with its obligations under Articles 5.1, 5.5, 5.6 or 2.2 of the *SPS Agreement* in respect of the ten measures concerned. Thus, we found that the ten measures are not inconsistent with the provisions of the *SPS Agreement* identified by Argentina. However, the relevant findings do not imply that Argentina's claim that the relevant product-specific measures are WTO-inconsistent should not be analysed under the *SPS Agreement*. As we have said earlier, the second type of measures challenged by Argentina in our view is conceptually the same as the type of product-specific measures challenged by the United States. Our findings above show that the measures challenged by the United States could, and in many cases did, give rise to an inconsistency with the provisions of Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*. Hence, we consider that Argentina's claim *could* be

[1670] We recall that Article 1.5 states that the provisions of the *TBT Agreement* do not apply to SPS measures within the meaning of Annex A(1) of the *SPS Agreement*.

[1671] Argentina's first written submission, paras. 374 and 450.

properly analysed under the *SPS Agreement*. Since Argentina's alternative claim under the *TBT Agreement* is relevant only in the event that we consider that the relevant product-specific measures should *not* be analysed under the *SPS Agreement*, we see no need to address Argentina's alternative claim under the *TBT Agreement* further.

(c) Conclusions

7.2528 In the light of the above, the Panel reaches the following conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the product-specific measures which are being challenged by Canada are inconsistent with Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement*. Accordingly, the Panel offers no findings under Articles 2.1, 2.2, 5.1.2 or 5.2.1, first part, of the *TBT Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the relevant ten product-specific measures challenged by Argentina are inconsistent with Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 of the *TBT Agreement*. Accordingly, the Panel offers no findings under Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 or 12 of the *TBT Agreement*.

## F. EC MEMBER STATE SAFEGUARD MEASURES

### 1. Introduction

7.2529 The Complaining Parties have made a series of claims concerning measures adopted by EC member States which allegedly prohibit the import, use of, or marketing of certain biotech products. These measures (hereafter "safeguard measures" or "member State measures") were adopted by EC member States on the basis of Article 16 of Directive 90/220[1672] (later replaced by Article 23 of Directive 2001/18[1673]) and Article 12 of Regulation 258/97.[1674]

(a) Safeguard measures in the context of the relevant EC approval procedures

7.2530 Where a biotech product has been approved for Community-wide marketing under Directives 90/220 or 2001/18, or Regulation 258/97, member States ordinarily may not prohibit or restrict trade in, or use of, that product on their respective territories, provided the conditions attached to the marketing approval are being met. Exceptionally, however, member States may provisionally adopt safeguard measures which prohibit or restrict trade in, or use of, biotech products which have been granted Community-wide marketing approval.

[1672] Exhibits US-25; CDA-18; ARG-4.
[1673] Exhibits US-24; CDA-17; ARG-3.
[1674] Exhibits US-26; CDA-19; ARG-5.

7.2531 Pursuant to Article 16 of Directive 90/220, a member State may provisionally restrict or prohibit the use and or sale of a product in its territory where it has "justifiable reasons to consider that a product which has been properly notified and has received written consent [...] constitutes a risk to human health or the environment".[1675] Safeguard measures adopted pursuant to Article 16 of Directive 90/220 have been maintained and reviewed on the basis of Article 23 of Directive 2001/18 since the entry into force of that Directive. Article 23 provides that a safeguard measure may be adopted where, "as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge", a member State has "detailed grounds for considering that a GMO as or in a product [...] constitutes a risk to human health or the environment [...]".[1676] Finally, Article 12 of Regulation 258/97 provides that a safeguard measure may be adopted where, "as a result of new information or a reassessment of existing information", a member State has "detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment [...]".[1677]

7.2532 The safeguard measures taken pursuant to Directives 90/220 and 2001/18, or Regulation 258/97, can be maintained only on a provisional basis, pending a full assessment at EC level.[1678] The member State adopting a safeguard measure must immediately inform the Commission and other member States of its measure.[1679] Upon notification of the safeguard measure, the Commission must take a decision with respect to that measure. Such decision will result either in the modification of the Community-wide marketing approval, or in the termination of the measure.[1680]

7.2533 According to the procedure laid down in the relevant provisions of Directives 90/220 and 2001/18, and Regulation 258/97[1681], the Commission, when making a decision on a safeguard measure which has been notified, is assisted for this purpose by the Regulatory Committee[1682] or by the Standing Committee on Foodstuffs, respectively.[1683] The Commission must submit a draft of the measure to be taken to the Regulatory Committee or the Standing Committee on Foodstuffs, which shall deliver their opinion on the draft within a time-limit which the chairman may lay down according to the urgency of the matter.[1684] If the draft measure is in accordance with the opinion of the Regulatory Committee or the Standing Committee on Foodstuffs, the Commission must adopt the draft measure. However, if the measure is not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission must submit without delay a proposal to the Council of

[1675] *See supra*, footnote 1672.
[1676] *See supra*, footnote 1673.
[1677] *Supra*, footnote 1674.
[1678] Article 16(1) of Directive 90/220; Article 23(1), 3rd paragraph of Directive 2001/18; and Article 12(1) of Regulation 258/97.
[1679] Article 16(1) of Directive 90/220; Article 23(1), 3rd paragraph of Directive 2001/18; and Article 12(1) of Regulation 258/97.
[1680] Article 21 of Directive 90/220. Under Directive 90/220, such a decision by the Commission must be taken within a period of three months from the time of notification of the measure. We note that there is no similar timeframe pursuant to Regulation 258/97.
[1681] Details of the procedures for Directives 90/220 and 2001/18, and Regulation 258/97 are described in section C.
[1682] Articles 21 of Directive 90/220 and 30(2) of Directive 2001/18.
[1683] Article 13 of Regulation 258/97.
[1684] Article 21 of Directive 90/220; Article 30(2) of Directive 2001/18; and Article 13 of Regulation 258/97. While Article 30(2) of Directive 2001/18 refers to Articles 5, 7 and 8 of Decision 1999/468, the European Communities notes that these provisions are similar to Article 21 of Directive 90/220 (EC reply to Panel question No. 84, para. 229).

Ministers on the measure to be taken. The Council must act on the proposal within a period of three months, failing which the Commission must adopt the proposed measure.[1685]

(b) Overview of the specific measures at issue

7.2534 The Complaining Parties make claims with respect to nine different safeguard measures, which they allege prohibit the importation or marketing of various biotech products. The nine measures were taken by six different member States, namely Austria, France, Germany, Greece, Italy and Luxembourg. For ease of reference, the safeguard measures are identified hereinafter by the name of the member State which has adopted the measure and the product(s) affected by such measure. Accordingly, the following safeguard measures are at issue in this dispute:

(1) *Austria – T25 maize*;
(2) *Austria – Bt-176 maize*;
(3) *Austria – MON810 maize*;
(4) *France – MS1/RF1 oilseed rape (EC-161)*;
(5) *France – Topas oilseed rape*;
(6) *Germany – Bt-176 maize*;
(7) *Greece – Topas oilseed rape*;
(8) *Italy – Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize*; and
(9) *Luxembourg – Bt-176 maize.*

7.2535 The safeguard measures at issue have all been taken pursuant to Article 16 of Directive 90/220, with the exception of the measure by Italy on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, which was adopted on the basis of Article 12 of Regulation 258/97.

7.2536 Each safeguard measure was notified to the Commission by the relevant member State with evidence allegedly supporting the adoption of the measure. On the basis of the information provided by the member State, the Commission requested in each case the opinion of the relevant EC scientific committee on whether this information constituted relevant scientific evidence that would cause the committee to consider that the product(s) at issue constituted a risk for human health or the environment. For each safeguard measure at issue, the relevant EC scientific committee reaffirmed its earlier assessment, or that of another EC scientific committee that the relevant products did not present any risks to human health or the environment. However, the Panel understands that as of the date of establishment of this Panel, no decision had been taken at Community level with regard to any of the safeguard measures at issue in this dispute. That is to say, no decision had been taken with regard to whether the Community-wide marketing approval for the relevant products should be modified, or whether the safeguard measures at issue should be terminated.[1686]

7.2537 The safeguard measures at issue in this dispute were still in force at the time of establishment of this Panel.[1687] However, the European Communities asserts that the safeguard measure adopted by Italy was repealed by a Decree adopted in October 2004.[1688]

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[1685] Article 21 of Directive 90/220; Article 30 of Directive 2001/18; and Article 13(4)(b) of Regulation 258/97.

[1686] According to Canada, the Commission indicated that it had called upon all EC member States with national measures in place restricting or prohibiting the marketing of EC-approved biotech products to lift or withdraw those measures. *See* Exhibits CDA-33 and -34.

[1687] EC reply to Panel question No. 101.

(c) Overview of Parties' claims and Panel's approach

7.2538 The **United States** is challenging all nine safeguard measures at issue in this case, as mentioned in paragraph 6 above. According to the United States, these safeguard measures are covered by the *SPS Agreement*. The United States argues that the safeguard measures violate various provisions of the *SPS Agreement*. In particular, the member States have failed to base their measures on a risk assessment and on scientific principles pursuant to Articles 5.1 and 2.2 of the *SPS Agreement*. Moreover, the member States have applied arbitrary or unjustifiable distinctions in their levels of protection against risks that have resulted in discrimination or a disguised restriction on international trade pursuant to Articles 5.5 and 2.3 of the *SPS Agreement*. The United States further argues that the safeguard measure prohibiting the importation of Topas oilseed rape adopted by Greece, in addition to violating various provisions of the *SPS Agreement*, violates Article XI:1 of the GATT 1994.

7.2539 **Canada** is challenging five safeguard measures, namely:

(1) *Austria – T25 maize*;
(2) *France – MS1/RF1 oilseed rape (EC-161)*;
(3) *France – Topas oilseed rape*;
(4) *Greece – Topas oilseed rape*; and
(5) *Italy – Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize*.

7.2540 Canada argues that the safeguard measures are SPS measures pursuant to Annex A of the *SPS Agreement*, and also affect international trade. Canada argues that the safeguard measures are not based on a risk assessment, as required by Article 5.1 of the *SPS Agreement*. Canada further argues that the safeguard measures violate Article 5.6, since the European Communities' own regulatory regime constitutes another measure, reasonably available taking into account technical and economic feasibility. Canada argues that the safeguard measures fail to meet any of the three requirements of Article 2.2, namely that they 1) be applied to the extent necessary to protect human, animal or plant life or health; 2) be based on scientific principles; and 3) not be maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. Consequently Canada argues that these measures violate Article 2.2. Finally, Canada argues that the safeguard measures are inconsistent with the European Communities' obligations under Article 5.5 of the *SPS Agreement*, and thus by implication, also violate Article 2.3.

7.2541 With respect to the Greek safeguard measure, Canada considers that it violates Article XI:1 of the GATT 1994. Canada further argues that the safeguard measures are inconsistent with Article III:4 of the GATT 1994. Canada also makes cumulative claims under the *TBT Agreement* arguing that the measures constitute technical regulations because they establish product specifications. In particular, Canada argues that the safeguard measures are inconsistent with Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

7.2542 **Argentina** makes claims with respect to six member State measures, as follows:

(1) *Austria – T25 maize*;
(2) *Austria – Bt-176 maize*;
(3) *Austria – MON810 maize*;
(4) *Germany – Bt-176 maize*;

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[1688] *See* EC reply to Panel question No. 160 and Exhibit EC-166. This was contested by Canada in their comments on other Parties' responses to Panel question 160, paras. 52-53.

(5) *Italy – MON810 maize, T25 maize, Bt-11 maize (EC-163)*[1689]; and
(6) *Luxembourg – Bt-176 maize.*

7.2543 Argentina argues that the safeguard measures are SPS measures pursuant to Annex A of the *SPS Agreement*, and also affect international trade. Argentina argues that the safeguard measures are not based on a risk assessment, as required by Article 5.1 of the *SPS Agreement*. Argentina further argues that the safeguard measures violate Article 5.6, since the European Communities' own regulatory regime constitutes another measure, reasonably available taking into account technical and economic feasibility. Argentina argues that the safeguard measures fail to meet the requirements of Article 2.2, which requires that a measure be applied "only to the extent necessary," while also requires that it be based on "sufficient scientific evidence." Consequently, the safeguard measures conflict with Article 2.2, and cannot be justified under the exception of Article 5.7. Finally, Argentina argues that the safeguard measures are inconsistent with the European Communities' obligations under Article 5.5 of the *SPS Agreement*, and thus by implication, also violate Article 2.3.

7.2544 Argentina argues that the safeguard measures are inconsistent with Article III:4 of the GATT 1994. Argentina also makes alternative claims under the *TBT Agreement* arguing that the measures constitute technical regulations because they establish product specifications. In particular, Argentina argues that the safeguard measures are inconsistent with Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

## 2. Analysis of the safeguard measures in the light of the *SPS Agreement*

7.2545 Before examining whether the relevant safeguard measures are inconsistent with the *SPS Agreement*, as claimed by the Complaining Parties, we must determine whether the *SPS Agreement* is applicable to these measures.

### (a) Applicability of the *SPS Agreement*

7.2546 We begin our examination of whether the *SPS Agreement* is applicable to the relevant safeguard measures by summarizing the Parties' general positions. In the light of these, we will outline how we will approach this issue, and subsequently address the applicability of the *SPS Agreement* measure-by-measure.

#### *(i) General*

7.2547 The **United States** argues that all the safeguard measures fall within the scope of the *SPS Agreement*. The general purpose of the member State measures can be inferred from the text of the EC legislation on which the measures are based. The overall objective set out in Article 16 of Directive 90/220 and Article 12 of Regulation 258/97 is the protection of human health and the environment. Since all measures were based on one of these provisions, it can be inferred that the measures were enacted for the purpose of protecting human health and the environment. Moreover, the sanitary or phytosanitary purpose of the member State measures can be found in the measures themselves, as well as in the justifications offered by the member States when the measures were adopted.

[1689] In respect of the safeguard measure imposed by Italy, while the complaints by the United States and Canada refer to four products, *i.e.*, Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize, the complaint by Argentina refers to only three products, *i.e.*, Bt-11 maize (EC-163), MON810 maize and T25 maize.

7.2548 The United States notes that the European Communities has not contested the fact that each of the member State measures was adopted at least for some reasons that fall within the scope of the *SPS Agreement*. It considers that the fact that the measures were adopted for some reasons covered by the *SPS Agreement* is sufficient to bring those measures within the scope of that Agreement. Annex A of the *SPS Agreement* makes it clear that "any measure" applied to protect against one of the enumerated risks falls within the scope of the Agreement. Annex A does not state that the measure needs to be exclusively applied to protect against only the enumerated risks, nor does the *SPS Agreement* state that a measure addressing one of the risks enumerated in Annex A loses its status as an SPS measure if the adoption of the measure is also supported by other rationales. The United States notes that in the *EC - Hormones* case, all parties agreed that the relevant EC Directives fell within the scope of the *SPS Agreement*, even though the Directives were not adopted solely to address alleged effects on human health.

7.2549 **Canada** argues that the safeguard measures it is challenging fall within the scope of paragraph 1(a) to (d) of Annex A of the *SPS Agreement*. Canada notes that the member State measures are intended to "protect" "human", "animal" or "plant" "life or health", or "to prevent or limit other damage" within their territories, as can be inferred from the relevant provisions of EC law on which the measures are based. According to Canada, this can also be inferred from the measures themselves, as well as from official statements made by government officials in relation to the passage or adoption of the measures. This evidence also supports the conclusion that these measures are designed to protect against "risks arising from" "the entry, establishment or spread" of "pests" or "disease-causing organisms" or "additives, contaminants, toxins or disease-causing organisms" in "food" or "feedstuffs". Although these terms are not defined in the *SPS Agreement*, their ordinary meaning, when read in context and in light of the object and purpose of the *SPS Agreement*, falls within the scope of the types of concerns intended to be addressed by the safeguard measures. More importantly, the text of the measures themselves, as well as the supporting documentation provided at the time the measures were adopted, demonstrate that the measures are SPS measures.

7.2550 **Argentina** argues that the purpose of the safeguard measures may be inferred from the Community legislation under which the measures were adopted. The relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2551 The **European Communities** notes that each of the safeguard measures was adopted for some reasons that fall within the scope of the *SPS Agreement*, and some reasons that fall outside the scope of that Agreement. According to the European Communities, if a WTO Member acts on the basis of two different objectives, one of which falls within the scope of the *SPS Agreement* and the other of which does not, these two measures are in effect different for WTO purposes. Therefore, the measure or part of the measure adopted for reasons that fall outside the scope of the *SPS Agreement* cannot be inconsistent with that Agreement. Only the measure, or part of the measure, adopted for reasons that fall within the scope of the *SPS Agreement* require further analysis. This is so even if the two different objectives sought to be achieved by a measure are reflected in a single document.

7.2552 The **Panel** recalls that pursuant to Article 1.1 of the *SPS Agreement*, the Agreement applies to "all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade".

7.2553 We recall once again that the term "SPS measures" is defined in Annex A(1) of the *SPS Agreement* as any measure applied:

> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures [...].

7.2554 In order to determine whether the *SPS Agreement* applies to the safeguard measures, the Panel must therefore determine (1) whether such measures are "sanitary or phytosanitary measures", or "SPS measures", as defined in Annex A of the *SPS Agreement*; and (2) whether these measures may, directly or indirectly, affect international trade.

7.2555 It is clear from the definition contained in Annex A(1) that one of the elements which determines whether a particular measure is an SPS measure is the purpose of the measure.[1690] A measure is an SPS measure if it is applied "to protect" life or health from certain enumerated risks, or if it is applied "to prevent or limit" certain other damage.

7.2556 In the case at hand, the Complaining Parties are challenging the maintenance in August 2003 of the relevant safeguard measures. We must therefore determine whether at that time each of the relevant safeguard measures served at least one of the purposes identified in the definition contained in Annex A of the *SPS Agreement*. In our view, a determination as to whether a particular safeguard measure was applied in August 2003 for one of the purposes enumerated in Annex A(1) must be made in the light of the specific circumstances of each case.

7.2557 We note that applicable EC legislation required the member States in question to provide justification for the adoption of their safeguard measures. We think that documents submitted by these member States by way of justification for the adoption of their measures are relevant to ascertaining the purposes of these measures.

7.2558 However, we consider that it would not be appropriate in this case to limit our inquiry to determining the purposes for which the safeguard measures were adopted. To begin with, we recall that our task in this case is to determine the purposes for which the relevant safeguard measures were maintained in August 2003. Furthermore, Annex A(1) does not refer to measures "adopted" for one of the enumerated purposes, but, more broadly, to measures "applied" for one of the enumerated purposes. Moreover, we see nothing in the *SPS Agreement* which would bar a panel from considering purposes which were not articulated by the member States when they adopted their safeguard

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[1690] As we have noted above in the context of our discussion of the general *de facto* moratorium on approvals, there are other elements which must be met for a measure to constitute an "SPS measure". *See supra*, para. 7.456.

measures.[1691] Finally, our approach is consistent with the view expressed by the Appellate Body that in identifying the purposes of a measure, panels need not seek to determine the subjective intent of the legislators or regulators who adopted the measure. According to the Appellate Body, the purposes of a measure may and should rather be ascertained on the basis of objective considerations, for instance by examining whether there is an objective relationship between the stated purposes and the text and structural features of the relevant measure.[1692]

7.2559 We recall that the safeguard measures were originally adopted on the basis of Article 16 of Directive 90/220 and Article 12 of Regulation 258/97. Both provisions make it clear that safeguard measures may be taken in case of a risk, or danger, to human health or the environment.[1693] The Complaining Parties argue that it can be inferred from this that the purpose of the safeguard measures is to protect against risks to human health or the environment. We note that the provisions of the *SPS Agreement* reflect similar objectives.[1694] We agree that the fact that the member States have invoked Article 16 of Directive 90/220 and Article 12 of Regulation 258/97 in support of their measures may, together with other elements, support the conclusion that these measures are applied to protect against risks to human health or the environment. However, the mere invocation of, and reference to, the aforementioned articles does not demonstrate, in and of itself, that a particular measure is in fact being applied for the purpose of protecting human health or the environment. Thus, we think it is necessary to make a separate assessment of the applicability of the *SPS Agreement* for each of the nine safeguard measures at issue.

7.2560 With these considerations in mind, we now turn to examine individually the nine safeguard measures at issue in this case.

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[1691] This does not mean, however, that we need to accept at face value assertions of purposes which are implausible in the light of all relevant circumstances.

[1692] *See, e.g.*, Appellate Body Reports, *Japan – Alcoholic Beverages II*, pp. 27-28 (including the statement that "[i]t is irrelevant that protectionism was not an intended objective if the particular tax measure in question is nevertheless, to echo Article III:1 [of the GATT 1994], "applied to imported or domestic products so as to afford protection to domestic production. This is an issue of how the measure in question is applied"); *Chile – Alcoholic Beverages*, paras. 62 and 71-72; and *US – Offset Act* (*Byrd Amendment*), para. 259. While these Appellate Body reports discussed claims under WTO agreements other than the *SPS Agreement*, the logic followed by the Appellate Body in these reports is applicable, in our view, to the issue we are considering here.

[1693] Article 16 of Directive 90/220: "1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision. 2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21."

Article 12 of Regulation 258/97: "1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. 2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force."

[1694] *See* e.g. Preamble for protection of human health; relevant ecological and environmental conditions to be taken into account in assessment of risks pursuant to Article 5.2 of the *SPS Agreement*.

*(ii) Austria – T25 maize*

7.2561 We begin with the safeguard measure applied by Austria on T25 maize. We recall that the product at issue was approved by the Commission for placing on the market in April 1998.[1695] In April 2000, Austria adopted an ordinance to prohibit commercialisation of T25 maize on its territory.[1696] Austria's safeguard measure, which was taken on the basis of Article 16 of Directive 90/220, was notified to the Commission in May 2000.[1697]

Is the Austrian safeguard measure on T25 maize an SPS measure?

7.2562 We start with the issue of whether the Austrian safeguard measure on T25 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2563 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2564 The **United States** notes that among the reasons set out to prohibit T25 maize, Austria cited the failure by the European Commission, at the time it approved the product, to set forth "protection for ecologically sensitive regions." According to the United States, a measure based on such justification is an SPS measure because it is applied "to protect animal life or health" from "disease-causing organisms"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2565 **Canada** notes that Austria sought to justify its ban on T25 maize on the grounds that pollen from the genetically modified variety could spread to fields containing non-biotech maize, giving rise to a risk of genetic transfer and the development of herbicide resistance in other species. Austria also cited the absence of a monitoring programme on the long-term effects of genetically altered plants, particularly in relation to the protection of ecologically sensitive regions, and the need for further testing of possible long-term ecological effects. Since these concerns relate to potential risks arising from T25 maize acting as a "pest" in relation to its surrounding environment, Canada argues that the Austrian safeguard measure is an SPS measure within the meaning of Annex A(1) of the *SPS Agreement*.

7.2566 **Argentina** argues that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed

[1695] Commission Decision 98/293.

[1696] We note that the text of the ordinance provides for an exception in cases where the product is to be immediately re-exported after handling and repackaging. Regulation No. 120, Federal Ministry for Social Protection and Generations, Ordinance issued on 28 April 2000 prohibiting the commercialization of the genetically altered corn Zea Mays L. T25 in Austria, approved by the European Commission on 22 April 1998 under Decision 98/293, Federal Gazette, vol. 2000, 28 April 2000 (Exhibits EC-160/At. 3_trans; CDA-76; US-53).

[1697] Exhibit EC-160/At. 3_trans.

for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2567 The **European Communities** asserts that the main reasons for which the Austrian measure affecting T25 maize was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.[1698]

7.2568 In examining the purposes for which Austria's safeguard measure on T25 maize is applied, the **Panel** will first consider the documents notified by Austria to the Commission in support of its safeguard measure. We note that Austria provided a justification for its safeguard measure in a document entitled "*Reasons for the decision of the Republic of Austria to prohibit the placing on the market of GM maize line T25* [...]" (hereafter the "Reasons document").

7.2569 In the Reasons document, Austria argued that the product had not been examined under realistic conditions of the use of the herbicide and of corresponding agricultural practices. [1699] Austria noted in this regard that neither the applicant's application seeking approval for the placing on the market of T25 maize nor the approval decision of the Commission foresaw a monitoring programme. In particular, Austria considered that special measures monitoring the spread of pollen to surrounding fields cultivated with conventional maize were missing. Austria further criticized the lack of a monitoring programme regarding the long-term effects of biotech plants and herbicides especially because of the fact that the conditions attached to the approval of T25 maize for Community-wide marketing did not foresee the protection of environmentally sensitive areas. An additional reason cited by Austria in support of its safeguard measure was that regional ecological aspects were not differentiated. Austria pointed out in this regard that the use of herbicide resistant plants such as T25 maize in areas of unavoidable applications of herbicides seemed to be useful, if good agricultural practices minimized the danger of the development of resistance in other species. Austria argued, however, that since mountain ecosystems are susceptible to accelerated soil erosion and rapid loss of habitat and genetic diversity, the use of herbicide resistant plants such as T25 maize in these areas should only take place after further investigations of possible long-term and secondary ecological effects.

7.2570 A document submitted by Austria to the Commission for an Experts Meeting held in Brussels in January 2004 (hereafter the "January 2004 document") also sheds light on the reasons for which Austria is applying its safeguard measure on T25 maize.[1700] In this document, Austria states that it adopted a safeguard measure because: (a) the environmental risk assessment was considered as insufficient, as it had not taken into account an integrated point of view of the use of herbicides under realistic conditions[1701]; and (b) possible long term effects and ecological aspects had not been scientifically assessed. In addition to these reasons, Austria cited other, more general concerns which in its view justify the precautionary approach embodied in Austria's safeguard measure. Specifically, Austria pointed out that the allergological and toxicological risk assessment concerning EC-approved biotech products such as T25 maize had been inadequate. Austria also noted that pending the report of the Working Group on antibiotic resistance marker genes set up by the European Communities in

[1698] Exhibit EC-155.
[1699] Exhibit EC-160/At. 3_trans.
[1700] Exhibit EC-158/At. 30.
[1701] It is not clear to the Panel if Austria is referring to a specific environmental risk assessment, and if so, which assessment.

accordance with Directive 2001/18, products containing such genes, including T25 maize, should not be placed on the market.

7.2571 Finally, we note that Austria's reasons for adopting the safeguard measure on T25 maize are also discussed in a letter addressed to the Commission in February 2004 by the Austrian Federal Minister for Health and Women. In that letter, Austria rejected a request by the Commission for the withdrawal of Austria's safeguard measure. In this context, Austria recalled that "[t]he crucial factors in the case of [the decision concerning] maize T25 were the absence of a supervisory programme and of an examination of the use of herbicide and agricultural practice. Both are related to the consideration of regional ecological characteristics and the protection of ecologically sensitive areas."[1702] Austria also reiterated its concern about inadequacies in the allergological and toxicological risk assessment concerning biotech products, such as T25 maize, which were submitted for approval under Directive 90/220[1703] and/or Regulation 258/97. Furthermore, Austria noted that it could not withdraw its safeguard measure on T25 maize in view of the fact that a coherent regulatory solution to the problem of coexistence had not yet been found.

7.2572 Based on the foregoing, we consider that at the time of review by the Panel, Austria applied its safeguard measure on T25 maize to address concerns about:[1704]

(1) the spread of pollen to cultivated surrounding fields (co-existence);
(2) long-term ecological effects in environmentally sensitive areas;
(3) allergenicity and toxicity; and
(4) the development of antibiotic resistance.

7.2573 The European Communities asserts that Austria's safeguard measure on T25 maize is also applied in view of concerns about labelling**.** This concern was not articulated by Austria in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Austria is applying its safeguard measure also to address the additional concern identified by the European Communities.

7.2574 Having determined the purposes for which Austria applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Austria's safeguard measure.

*Spread of pollen to cultivated surrounding fields (co-existence)*

7.2575 We begin with the purpose of preventing the spread of pollen to surrounding areas cultivated with conventional maize. We observe that Austria does not claim that its safeguard measure on T25 maize is intended to prevent environmental effects associated with out-crossing between T25 maize and conventional maize. Rather, Austria emphasizes the need for "special measures monitoring the possible – mostly regarded as safe – spread of pollen to fields in the surroundings cultivated with conventional maize".[1705] As Austria in this statement explicitly notes the lack of compelling safety

[1702] Exhibit EC-158/At. 31_trans.

[1703] The document submitted by Austria actually refers to Regulation 2001/18, which appears to be an error.

[1704] We note that some of these concerns were articulated by Austria in documents which post-date the date of establishment of this Panel. However, we see no grounds for considering that these plausible concerns did not underlie the safeguard measure at issue already in August 2003.

[1705] Exhibit EC-160/At. 3, p. 4.

concerns, we understand this statement to refer to concerns over the possible loss of economic value to farmers, who due to the existence of unwanted, out-crossed plants in their fields, can no longer market their crops as non-GM crops.

7.2576 In Section VII.C we have found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". This includes cross-breeds between GM maize and conventional maize which grow in a conventional maize field.

7.2577 In view of these findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to prevent economic damage resulting from the entry, establishment or spread of cross-breeds between T25 and conventional maize in cultivated surrounding maize fields, falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

*Long-term ecological effects in environmentally sensitive areas*

7.2578 The Panel turns now to the next objective stated by Austria for prohibiting the placing on the market of T25 maize, namely, Austria's concerns over long-term ecological effects. Austria includes in this category of concerns secondary ecological effects. The Panel understands the term "secondary ecological effects" to refer to indirect environmental effects which might be caused by the cultivation of T25 maize.

7.2579 In Section VII.C we have addressed concerns that GM plants might crowd out or eliminate other plants, due to a potential competitive advantage, invasiveness or persistence, thus affecting the genetic diversity of remaining plant populations and putting at risk the survival of certain plant species. In relation to these concerns, we stated that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a), as it would be applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

7.2580 We further found that to the extent that GM plants may result in changes in plant populations, this may increase or decrease the food available for particular animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce. We stated that, by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1)(a), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a).

7.2581 We also found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as herbicide resistance) resulting from transfer of genetic material from a GM plant.

7.2582 Moreover, we addressed potential risks to the environment, including to farmland wildlife, resulting from a change in weed control practices (the application of a herbicide where none was used before the increased application of a herbicide, or the application of a different, more harmful herbicide). We said that to the extent a measure is applied to avoid adverse effects on the life or health of animals or plants which arise from the management techniques associated with GMOs, such a measure falls within the scope of Annex A(1)(a), in that it can be viewed as a measure applied to

protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".

7.2583 Finally, we found that to the extent a measure seeks to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health, including on geochemical processes, such a measure can be considered to be covered by Annex A(1)(d), inasmuch as it can be viewed as a measure which is applied to prevent or limit "other damage" from the entry, establishment or spread of "pests". As noted earlier, the GMOs themselves or cross-breeds of GM plants might qualify as the relevant pests, or other plants or animals might become pests as a result of the release of GMOs into the environment. Furthermore, we said that to the extent that a measure is applied to avoid adverse effects arising from the management techniques associated with GMOs other than damage to the life or health of animals or plants, that measure can be considered as a measure applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests".

7.2584 In view of the above findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to avoid potential long-term ecological effects of the release into the environment of T25 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Allergenicity and toxicity*

7.2585 We turn now to Austria's stated concern regarding potential risks of allergenicity and toxicity associated with T25 maize.

7.2586 In Section VII.C we have found that Annex A(1)(b) covers measures applied to protect the life or health of humans or animals (not including target organisms) from risks arising from toxins produced in GM plants which are foods or feedstuffs. Furthermore, we found that to the extent that a measure seeks to protect humans and animals from allergenic effects of GM plants used as or in foods, that measure can be considered to be a measure applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs and, as such, would fall within the scope of Annex A(1)(b).

7.2587 We also recall our view that if interaction with, and exposure to, GMOs other than as or in a food produced allergenic effects in persons, the GMOs in question could be considered "pests" within the meaning of Annex A(1). We therefore found that to the extent that a measure seeks to avoid the entry, establishment or spread of allergenic GM plants, that measure can be considered to be a measure applied to protect human life or health from risks arising from the entry, establishment or spread of GM plants *qua* "pests". As such, it would fall within the meaning of Annex A(1)(c).

7.2588 In view of the above findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to protect from potential allergenic and toxicologic effects associated with T25 maize, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

*Development of antibiotic resistance*

7.2589 We turn finally to the purpose of managing potential risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of T25 maize. We recall our discussion in Section VII.C regarding antibiotic resistance marker genes (ARMG). More particularly, we recall that in our view, the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of

medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2590 In Section VII.C we have found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2591 In view of the above findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to avoid risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of T25 maize, falls within the scope of Annex A(1)(a) and (b) of the SPS Agreement.

*Conclusion with regard to the purpose of the safeguard measure*

7.2592 In the light of the above considerations, we conclude that the safeguard measure applied by Austria with respect to T25 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the safeguard measure

7.2593 We now turn to the issue of the form and nature of the Austrian safeguard measure on T25 maize. We start by recalling the Parties' arguments on this matter.

7.2594 The **United States** notes that the Austrian measure is in the form of an "ordinance", which is defined as "an authoritative decree or command"[1706]. The United Stated further notes that a decree is among the types of measures explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2595 **Canada** argues that the measure falls within the scope of "laws, decrees, regulations, requirements and procedures." As indicated by the use of the word "include", Annex A provides a non-exhaustive list of the forms that an SPS measure can take. The Austrian measure takes the form of an "ordinance", a type of measure which is not among those expressly enumerated in Annex A, but which is nonetheless legally binding and lawfully promulgated by the central government authorities. The term ordinance is also defined as synonymous to the word "decree", which is specifically referred to in Annex A(1).

7.2596 **Argentina** notes that an "ordinance" is defined as an "authoritative decree or command", and that a decree is one of the types of measures specifically mentioned in Annex A of the *SPS Agreement*.

[1706]*The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 2017.

7.2597 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered as "requirements". The second example would constitute a negative requirement.

7.2598 We note that the Austrian safeguard measure on T25 maize was implemented by Austria through an ordinance to prohibit commercialization of T25 maize on its territory. Annex A(1) does not specifically refer to "ordinances". As we have pointed out, this fact alone does not necessarily mean that Austria's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Austria's ordinance clearly is a measure attributable to the Austrian Government. It is also not in dispute that the ordinance is legally binding. We therefore consider that, for the purposes of Annex A(1), the Austrian ordinance may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2599 In respect of the nature of the Austrian measure, we note that the ordinance prohibits the marketing of T25 maize. As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2600 We therefore conclude that the safeguard measure taken by Austria with respect to T25 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2601 We have now considered Austria's safeguard measure on T25 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Austria's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure taken by Austria with respect to T25 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2602 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Austrian safeguard measure could be considered to embody more than one SPS measure. However, neither the Complaining Parties nor the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Austrian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Austrian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2603 We now turn to the issue of whether Austria's safeguard measure on T25 maize is a measure that may affect international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Austria's safeguard measure on T25 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2604 The **United States** argues that the measure adopted by Austria prohibits the "placing on the market" of T25 maize, thereby effectively blocking the importation of the product.

7.2605 **Canada** argues that the measure prohibits commercialization of T25 maize and bans its importation, except where the imported product is "immediately" exported "after possible handling and repackaging" in Austria. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2606 **Argentina** notes that since the safeguard measure prevents access of T25 maize to Austria, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2607 The **Panel** notes that pursuant to Article 1.1 of the *SPS Agreement*, it is not necessary to demonstrate that an SPS measure has an actual effect on trade. Article 1.1 merely requires that an SPS measure "may, directly or indirectly, affect international trade".

7.2608 Austria's decision to apply a safeguard measure on T25 maize is contained in the text of the Ordinance that entered into force on 29 April 2000.[1707] According to the text of the Ordinance, Austria's decision prohibits the placing on the Austrian market of T25 maize. In our understanding, the prohibition applies also to imports of T25 maize from outside the European Communities.[1708]

7.2609 In view of the fact that Austria's safeguard measure prohibits imports of T25 maize, we have no difficulty concluding that the safeguard measure by Austria is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2610 In the light of the above, the Panel reaches the following overall conclusions:

(a) DS291 (United States)

(b) With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Austrian safeguard measure on T25 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement.*

[1707] Exhibit EC-160/At. 3.

[1708] We note that this is subject to an exception for imported T25 maize that is immediately exported after handling and repackaging in Austria.

(c) DS292 (Canada)

(d) With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the Austrian safeguard measure on T25 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(e) DS293 (Argentina)

(f) With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Austrian safeguard measure on T25 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(iii) Austria – Bt-176 maize*

7.2611 We now turn to the safeguard measure applied by Austria on Bt-176 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1709] The product was authorized by the EC Commission in 1996.[1710] Austria adopted an Ordinance to prohibit the sale of Bt-176 maize on its territory in February 1997 on the basis of Article 16 of Directive 90/220.[1711] Austria notified its Decision to the Commission on 14 February 1997.

Is the Austrian safeguard measure on Bt-176 maize an SPS measure?

7.2612 We start with the issue of whether the Austrian safeguard measure on Bt-176 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2613 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2614 The **United States** recalled that in its decision to adopt the measure, Austria noted its concern with regard to the effect of Bt toxin on non-target organisms and the potential transfer of antibiotic resistant genes to humans and animals. According to the United States, a measure based on such justification is an SPS measure because it is applied "to protect animal life or health" from "disease-causing organisms"; "to protect human life or health" from "toxins" or "disease-causing organisms in foods"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2615 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed

[1709] C/F/94/11-03.
[1710] Commission Decision 97/98 (Exhibits US–97; ARG–37).
[1711] Regulation No. 45 of the Federal Ministry for Consumer Health and Protection, 13 February 1997.

for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2616 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.[1712]

7.2617 In examining the purposes for which Austria's safeguard measure on Bt-176 maize is applied, the **Panel** will first consider the document notified by Austria to the Commission in support of its safeguard measure in February 1997, hereafter referred to as Austria's "Reasons document".[1713] In the Reasons' document, Austria stated that "new scientific results have questioned the present scientific possibility of a conclusive evaluation of the mechanism of gene transfer, as well as the development of resistance to Bt toxin. Accordingly, possible risks are very hard to assess and should be avoided at the present state of the scientific discussion."[1714] Austria considered that, in the case of Bt-176 maize, approving the product despite the uncertainties regarding both the ampicillin resistance as well as the resistance against the Bt toxin without any legally binding resistance management programme was in conflict with the principle of precaution.[1715] In particular, Austria noted that evidence on "the impact of a potential gene transfer of the *bla*-gene/b-lactamase and potential induction of resistance in bacteria on the therapy of humans and animals with antibiotics remains not fully conclusive."[1716]

7.2618 We note that Austria also notified the Commission in May 1997 of the results of two studies concerning the possible adverse effects on the environment due to the cultivation of Bt maize.[1717] In the cover letter, Austria states that "[...] these studies prove that pests may evolve (*sic*) resistance against *Bt* toxins much faster than previously expected, due to the fact that transgenic crops producing insecticidal proteins from *Bt* [...] are being grown commercially."[1718]

7.2619 Furthermore, in the cover letter addressed to the Commission at the time of notification of the measure, Austria indicated that it maintained its position that "the labelling laid down in the Commission's decision is insufficient", and that "[c]onsumers should be informed precisely about the fact that this product has been genetically modified."[1719]

7.2620 The January 2004 document submitted by Austria to the Commission also sheds light on the reasons for which Austria is applying its safeguard measure on Bt-176 maize.[1720] In this document, Austria states that it adopted its safeguard measure regarding Bt-176 maize because: "(a) [t]he transgenic maize line contains the ampicillin-resistance gene including its bacterial regulatory sequences. The probability of gene transfer of a functional *bla*-construct into bacteria – even though it is considered low – has to be taken into account for the risk assessment, because the spreading of antibiotic resistance is unacceptable; and (b) [t]he environmental risk assessment has been considered

[1712] Exhibit EC-155.
[1713] Exhibit EC-158/At. 7.
[1714] *Ibid*, p. 5.
[1715] *Ibid.*
[1716] Exhibit EC-158/At. 7 p. 6.
[1717] Exhibit EC-158/At. 10. The two studies referred to by Austria are contained in Exhibits EC-158/At. 11-12.
[1718] Exhibit EC-158/At. 10.
[1719] Exhibit EC-158/At. 7.
[1720] Exhibit EC-158/At. 30.

as insufficient: the possible unintended effects of the Bt-toxin on non-target organisms and the possible resistance-development in insects, *e.g*. the European corn borer, has not been thoroughly assessed".[1721] In addition to these reasons, Austria cited other, more general concerns which in its view justify the precautionary approach embodied in Austria's safeguard measure. Specifically, Austria pointed out that the allergological and toxicological risk assessment concerning EC-approved biotech products such as Bt-176 maize had been inadequate. Austria also noted that pending the report of the EC working group on antibiotic resistance marker genes established pursuant to Directive 2001/18, products containing such genes, including Bt-176 maize, should not be placed on the market.

7.2621 We note that Austria's concerns for adopting a safeguard measure on Bt-176 maize are also discussed in a letter addressed to the Commission in February 2004 by the Austrian Federal Minister for Health and Women. In that letter, Austria rejected a request by the Commission for the withdrawal of Austria's safeguard measure. In this context, Austria recalled that "[t]he Austrian decision concerning Bt-176 maize was based on health doubts regarding the ampicillin-resistant gene (*bla*) with a bacterial promoter and the possible resistance formation of insects to the bacillus thuringiensis (Bt) protein. There was also a lack of clarity regarding the ecological effects of herbicide resistance and inadequate designation."[1722] Austria also reiterated its concern about inadequacies in the allergological and toxicological risk assessment concerning biotech products, such as Bt-176 maize, which were submitted for approval under Directive 90/220 and/or Regulation 258/97. Furthermore, Austria noted that it could not withdraw its safeguard measure on T25 maize in view of the fact that a coherent regulatory solution to the problem of co-existence had not yet been found. The Austrian letter notes in this respect that in June 2003 a resolution had been approved in the Austrian parliament calling on the Austrian Federal Government to refrain from approving new GM plants, especially in relation to their cultivation, until a coherent solution was found on this issue.

7.2622 Based on the foregoing, we consider that at the time of review by the Panel, Austria applied its safeguard measure on Bt-176 maize to address concerns about:[1723]

(1) the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans and animals;
(2) the development of resistance to Bt toxin in insects;
(3) effects on non-target organisms;
(4) environmental effects of herbicide resistance;
(5) co-existence;
(6) allergenicity and toxicity; and
(7) insufficient labelling.

7.2623 Having determined the purposes for which Austria applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Austria's safeguard measure.

[1721] Exhibit EC-158/At. 30, p. 2.
[1722] Exhibit EC-158/At. 31_trans.
[1723] We note that some of these concerns were articulated by Austria in documents which post-date the date of establishment of this Panel. However, we see no grounds for considering that these plausible concerns did not underlie the safeguard measure at issue already in August 2003.

*Transfer of the bla-ampicillin resistance gene to bacteria of the intestine of humans or animals*

7.2624 The Panel begins with Austria's stated concern regarding the potential transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of Bt-176 maize. The concern identified by Austria with regard to Bt-176 is similar to that identified by Austria with regard to its safeguard measure on T25 maize, discussed above. We recall our discussion in Section VII.C regarding antibiotic resistance marker genes, and in particular our view that the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2625 In Section VII.C we have found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2626 Thus, consistent with the Panel's reasoning above in the context of Austria's safeguard measure on T25 maize, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

*Development of resistance to Bt toxin in insects*

7.2627 We turn now to another objective stated by Austria for prohibiting the placing on the market of Bt-176 maize, namely the managing of potential risks associated with the development of resistance to Bt toxin in both target and non-target insects. We understand the concern identified by Austria to be that resistance in insects to Bt toxin may develop due to frequent exposure to this pesticide (the Bt toxin) and that the development of high levels of resistance in insect populations might require the application of a pesticide where none was used before, the increased application of a pesticide, or the application of more harmful pesticides, to control the resistant populations and that this might have adverse effects on the environment.

7.2628 We recall our analysis in Section VII.C regarding the development of pesticide-resistance in target organisms. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We found that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2629 In view of the above findings, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to protect from potential risks associated with the development of resistance to Bt toxin in insects due to the cultivation of Bt-176 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Effects on non-target organisms*

7.2630 We now consider Austria's stated objective of managing risks associated with potential effects on non-target organisms, other than risks associated with the development of resistance in insects as addressed above. As we noted earlier, we understand "non-target" organisms to mean plants and animals (including insects) which are not themselves the organisms farmers seek to control or eliminate through the cultivation of GM crops, but which are affected by the cultivation of the GM crop, including through consumption of the GM plants or components thereof (*e.g.*, pollen).

7.2631 We recall our conclusions in Section VII.C that a GM crop that is eaten by animals can be considered to be a "food" for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. As we previously noted, a poisonous substance, such as the Bt toxin, which is produced by a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b). We determined on that basis that measures applied to protect the life or health of animals (not including target organisms) from risks arising from toxin produced in GM plants are covered by Annex A(1)(b).

7.2632 Moreover, we indicated in Section VII.C our view that if a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms, even if the non-target organisms do not eat the GM plant, *e.g.* through exposure other than through ingestion of food, the GM plant could be considered a "pest" within the meaning of Annex A(1)(a). Thus, a measure applied to protect from risks arising from such exposure to GM plants would, in our view, fall within the scope of Annex A(1)(a).

7.2633 In addition, in Section VII.C we concluded that to the extent that GM plants may result in changes in animal or plant populations, this may increase or decrease the food available for particular non-target animal populations and thus alter the fitness and health of these animal populations, which may in turn lead to further deleterious effects on the life or health of animals or other plants. We also recall our conclusion that by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a). Furthermore, we found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as insecticidal traits) resulting from transfer of genetic material from a GM plant.

7.2634 In view of these findings, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential risks to the health of non-target organisms from the consumption of Bt-176 maize, falls within the scope of Annex A(1)(b) of the *SPS Agreement*. Furthermore, to the extent that Austria's safeguard measure is applied to avoid other potential risks to the life or health of non-target organisms arising directly or indirectly from Bt-176 maize (*i.e.*, risks unrelated to the ingestion of Bt-176 maize as food), it falls within the scope of Annex A(1)(a) of the *SPS Agreement*.

*Environmental effects of herbicide resistance*

7.2635 Another concern raised by Austria concerns the environmental effects of herbicide resistance. We understand this to be a concern about the environmental effects of Bt-176 maize which contains a herbicide resistance marker gene.

7.2636 In Section VII.C we have found that cross-breeds between conventional and GM plants, including herbicide-resistant plants, could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide resistance) and harm animal or plant life or health or result in other damage. We have determined on that basis that measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) from the entry, establishment or spread of cross-breeds with undesired traits resulting from the transfer of genetic material from a GM plant fall within the scope of Annex A(1)(a), while measures applied to prevent "other damage" to the environment from the entry, establishment or spread of cross-breeds fall within the scope of Annex A(1)(d).

7.2637 In addition, we recall that one possible concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or different, more toxic herbicides, to control the resistant weeds. We determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We deduced from this that measures applied to avoid such indirect adverse effects on the environment fall within the scope of Annex A(1)(a) and (d).

7.2638 Furthermore, in Section VII.C we have found that to the extent a measure is applied to avoid adverse effects on the life or health of animals or plants which arise from particular management (weed control) practices associated with GMOs, including herbicide resistant GMOs, such a measure falls within the scope of Annex A(1)(a), in that it can be viewed as a measure applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests". Similarly, we said that to the extent that a measure is applied to avoid adverse environmental effects arising from management (weed control) practices associated with GMOs other than damage to the life or health of animals or plants, that measure can be considered as a measure applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests" and would thus also be covered by Annex A(1)(d).

7.2639 In view of our findings above, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks to the environment arising from herbicide resistance, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Co-existence*

7.2640 We now turn to Austria's stated concern about co-existence. We understand this to be a concern that farmers cultivating conventional maize might experience a loss of economic value of their crop due to the existence of unwanted genetically modified maize plants in their fields (contamination). The loss would result from the circumstance that the farmers might no longer be able to market their crops as non-GM crops.

7.2641 In Section VII.C we have found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". Such plants include cross-breeds

between GM maize and conventional maize which grow in a conventional maize field as a result of pollen dispersal. Such plants further include GM maize plants growing in a conventional maize field as a result of unintentional dispersal of GM seed. Thus, we consider that to the extent Austria's safeguard measure on Bt-176 maize is applied to prevent economic damage resulting from the contamination of conventional maize due to the entry, establishment or spread of Bt-176 maize (via dispersal of GM seed), or of cross-breeds between Bt-176 maize and conventional maize (via dispersal of GM pollen), in cultivated conventional maize fields, it falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

7.2642 In view of the above findings, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to prevent or limit damage from the possible contamination of conventional maize by Bt-176 maize, falls within the scope of Annex A(1)(d) of the *SPS Agreement*.

*Allergenicity and toxicity*

7.2643 We now turn to Austria's stated concern regarding the potential risks of allergenicity and toxicity associated with Bt-176 maize. We recall our analysis related to allergens and toxins in Section VII.C and our analysis of this concern in the context of Austria's safeguard measure on T25 maize.

7.2644 In particular, we recall that in Section VII.C we have found that to the extent that a measure seeks to protect humans and animals from allergenic effects of GM plants used as or in foods or feedstuffs, that measure can be considered to be a measure applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs and, as such, would fall within the scope of Annex A(1)(b). We furthermore recall our view that if interaction with, and exposure to, GMOs other than as or in a food or feedstuff produced allergenic effects in persons, the GMOs in question could be considered "pests" within the meaning of Annex A(1)(c).

7.2645 Consistent with our reasoning above, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential allergenic or toxic effects, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

*Insufficient labelling*

7.2646 Finally, we turn to Austria's stated concern regarding insufficient labelling of Bt-176 maize. We recall that Austria considered that "the labelling laid down in the Commission's decision is insufficient" and that "[c]onsumers should be informed precisely about the fact that this product has been genetically modified."[1724] The Commission's decision to which Austria refers stipulates that the label of each package of seeds of Bt-176 maize is to indicate that the product "protects itself against corn borers", and that it "has increased tolerance to the herbicide glufosinate-ammonium".[1725] The preamble to the decision further notes that there were no safety grounds for mentioning on the label that the product has been obtained by genetic modification techniques. Thus, it appears that contrary to the Commission, Austria wanted the label to indicate the presence of GMOs, in addition to providing the information the Commission required to be indicated on the label of each package of seeds.

[1724] Exhibit EC-158/At. 7.
[1725] Exhibits US-97; ARG-37.

7.2647 We note that Austria stated that the explicit identification of the presence of GMOs which it was seeking would be for the information of consumers of Bt-176 maize. We also note, however, that Austria's letter to the Commission states that Austria's safeguard measure on Bt-176 maize is taken in accordance with Article 16 of Directive 90/220. To recall, Article 16 provides that member States may take safeguard measures in cases where there are justifiable reasons to consider that an approved biotech product constitutes a risk to human health or the environment. Article 16 does not authorize a member State to restrict or prohibit the use and/or sale of an approved biotech product merely because a labelling requirement specified in the written consent for the placing on the market of that biotech product does not ensure consumers' freedom of choice (with regard to the consumption of GM products *vs*. non-GM products).

7.2648 Since Austria specifically claimed to be acting in accordance with the provisions of Article 16 of Directive 90/220, we consider that Austria's reference to consumer information should be read in the light of, and together with, Austria's reference to Article 16. Indeed, in our view, Austria's argument that consumers should be explicitly informed about the presence of GMOs can be understood as an argument that identification of the presence of a GMO would help protect notably from unanticipated adverse effects on human health which might arise from the consumption of Bt-176 maize.[1726] As we have indicated in Section VII.C, explicit identification of the presence of a GMO alerts and sensitises users of a product containing or consisting of a GMO to the possibility that any observed adverse effects of the product on human health might be attributable to the presence of a GMO as opposed to other factors. In view of the foregoing elements, we consider that Austria's concern about insufficient labelling reflects a concern about risks to consumer health arising from the consumption of Bt-176 maize.

7.2649 This interpretation of Austria's labelling concern is consistent with the provisions of Directive 90/220. While Directive 90/220 does not require a statement on a label to the effect that a GMO is present in a product, it does not state that such a requirement may not be imposed as part of the conditions attached to the written consent to placing on the market. Furthermore, we recall that Directive 2001/18 requires labelling to indicate the presence of GMOs. We find in Section VII.C that this requirement could be presumed to be applied to protect human health and the environment from possible unanticipated effects of GMOs. Thus, our interpretation of Austria's labelling concern is consistent with the kind of general labelling requirement which was subsequently imposed by Directive 2001/18.

7.2650 We refer to our analysis in Section VII.C of labelling to indicate the presence of GMOs. As noted in that section, we are of the view that labelling to indicate the presence of GMOs imposed for the purpose of protecting human health from unanticipated effects of GMOs falls within the scope of Annex A(1)(b) or (c) of the *SPS Agreement*, depending on what the adverse effects would be.

7.2651 In view of our findings above, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid adverse effects on human health (due to the potential transfer of ARMG to gut bacteria and possible allergenicity and toxicity) which in Austria's view were not adequately avoided by the labelling requirements imposed by the Commission, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

[1726] In view of Austria's reference to "consumers", we are assuming that Austria was concerned with unanticipated adverse effects on human health from consumption of Bt-176 maize, and not with other adverse effects on human health, on animals or on the environment.

*Conclusion with regard to the purpose of the safeguard measure*

7.2652 In the light of the above considerations, we conclude that the safeguard measure applied by Austria with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2653 We now turn to the issue of the form and nature of Austria's safeguard measure on Bt-176 maize.

7.2654 We note that the arguments presented by the United States and Argentina regarding the form and nature of Austria's safeguard measure on Bt-176 maize are the same as for Austria's safeguard measure on T25 maize.

7.2655 Thus, as in the case of Austria's safeguard measure on T25 maize we conclude that the safeguard measure applied by Austria with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2656 We have now considered Austria's safeguard measure on Bt-176 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Austria's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure taken by Austria with respect to Bt-176 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2657 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Austrian safeguard measure could be considered to embody more than one SPS measure. However, neither the United States, nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Austrian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Austrian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2658 We now turn to the issue of whether Austria's safeguard measure on Bt-176 maize is a measure that may affect international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Austria's safeguard measure on Bt-176 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2659 The **United States** argues in this regard that the measure adopted by Austria prohibits the "placing on the market" of Bt-176 maize, thereby effectively blocking the importation of the product.

7.2660 **Argentina** notes that since the safeguard measure prevents access of Bt-176 maize to Austria, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2661 The **Panel** notes that the arguments of the parties regarding the effects on trade of Austria's safeguard measure on Bt-176 maize are essentially the same as their arguments with respect to Austria's measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's safeguard measure on T25 maize in paragraphs 7.2603-7.2609 above. In view of the fact that Austria's measure prohibits imports of Bt-176 maize, we have no difficulty concluding that Austria's safeguard measure is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2662 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Austrian safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Austrian safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(iv) Austria – MON810 maize*

7.2663 We now turn to the safeguard measure applied by Austria on MON810 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1727] The product was authorized for all uses by the European Commission in 1998.[1728] In June 1999, Austria adopted an Ordinance to prohibit the sale of MON810 maize on its territory pursuant to Article 16 of Directive 90/220.[1729]

Is the Austrian safeguard measure on MON810 maize an SPS measure?

7.2664 We start with the issue of whether the Austrian safeguard measure on MON810 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

[1727] C/F/95/12-02.
[1728] Commission Decision 98/294.
[1729] Regulation No. 175, Federal Ministry for Women's Issues and Consumer Protection, Ordinance issued on 10 June 1999 prohibiting the entry of MON810 maize into Austria.

Purpose of the safeguard measure

7.2665 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2666 The **United States** notes that in its decision to adopt a safeguard measure to prohibit MON810 maize, Austria referred to the adverse effects of Bt toxin on non-target organisms. Austria also expressed a concern that insects could develop resistance to the Bt toxin, thus becoming more difficult to manage and control.[1730] According to the United States, a measure based on such justification is an SPS measure because it is applied "to protect animal life or health" from "disease-causing organisms"; "to protect human life or health" from "toxins" or "disease-causing organisms in foods"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2667 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2668 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; development of resistance; biodiversity; monitoring; labelling; co-existence; and human and animal health.[1731]

7.2669 In examining the purposes for which Austria's safeguard measure on MON810 maize is applied, the **Panel** will first consider the document notified by Austria to the Commission in support of its safeguard measure, hereafter referred to as Austria's Reasons document. In this document, Austria notes that its objections regarding the assessment of MON810 maize concern the possible unintended effects of the Bt toxin on non-target organisms, and the possible development of Bt resistance in insects, such as the European corn borer.[1732]

7.2670 The concerns of Austria with respect to MON810 maize are further identified in a January 2004 document as follows: "(a) [a] risk assessment on indirect and long term effects of the Bt toxin is missing; and (b) [t]he environmental risk assessment has been considered as insufficient: the possible unintended effects of the Bt-toxin on non-target organisms and the possible resistance-development in insects [...] has not been thoroughly assessed".[1733] In addition to these reasons, Austria cited other, more general concerns which in its view justify the precautionary approach embodied in Austria's safeguard measure. Specifically, Austria pointed out that the allergological and toxicological risk assessment concerning EC-approved biotech products such as MON810 maize had been inadequate. Austria also noted that pending the report of the EC Working Group on antibiotic resistance marker genes (ARMG), biotech products containing such genes, such as MON810 maize, should not be placed on the market.

[1730] US first written submission, para. 157.
[1731] Exhibit EC-155.
[1732] Exhibit EC-159/At. 3_trans., pages 5-6.
[1733] Exhibit EC-159/At. 30, p. 2.

7.2671 We note that Austria's concerns for adopting a safeguard measure with regard to MON810 maize are also discussed in a letter addressed to the Commission in February 2004 by the Austrian Federal Minister for Health and Women. In this letter, Austria rejected a request by the Commission that Austria withdraw its safeguard measure. In this context, Austria recalled that "[t]his prohibition on cultivation was issued in the light of scientific discoveries concerning the effects of the *bacillus thuringiensis* (Bt) protein, which is directed at insects, on monarch butterflies in the US and other non-target organisms. In addition, Austria referred to the question of resistance formation, as in the case of Bt-176 maize."[1734] Austria also reiterated its concern about inadequacies in the allergological and toxicological risk assessment concerning biotech products, such as MON810 maize, which were submitted for approval under Directive 90/220 and/or Regulation 258/97. Furthermore, Austria noted that it could not withdraw its safeguard measure on MON810 maize in view of the fact that a coherent regulatory solution to the problem of co-existence had not yet been found. The Austrian letter notes in this respect that in June 2003 a resolution had been approved in the Austrian parliament calling on the Austrian Federal Government to refrain from approving new GM plants, especially in relation to their cultivation, until a coherent solution was found on this issue.

7.2672 Based on the foregoing, we consider that at the time of review by the Panel, Austria applied its safeguard measure on MON810 maize to address concerns about:[1735]

(1) the effects on non-target organisms, including indirect and long-term effects;
(2) the development of resistance to Bt toxin in insects, including indirect and long-term effects of insect resistance;
(3) allergenicity and toxicity;
(4) the development of antibiotic resistance; and
(5) co-existence.

7.2673 The European Communities asserts that Austria's safeguard measure on MON810 maize is also applied in view of concerns about labelling. This concern was not articulated by Austria in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Austria is applying its safeguard measure to address this concern asserted by the European Communities.

7.2674 Having determined the purposes for which Austria applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Austria's safeguard measure.

*Effects on non-target organisms, including indirect and long-term effects*

7.2675 We turn first to Austria's stated concern regarding the potential effects on non-target organisms associated with MON810 maize. We recall our analysis related to effects on non-target organisms in Section VII.C and our analysis of this concern in the context of Austria's safeguard measure on Bt-176 maize.

[1734] Exhibit EC-158/At. 31.
[1735] We note that some of these concerns were articulated by Austria in documents which post-date the date of establishment of this Panel. However, we see no grounds for considering that these plausible concerns did not underlie the safeguard measure at issue already in August 2003.

7.2676 We recall our conclusions in Section VII.C that a GM crop that is eaten by animals can be considered to be a "food" for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. As we previously noted, a poisonous substance, such as the Bt toxin, which is produced by a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b). We determined on that basis that measures applied to protect the life or health of animals (not including target organisms) from risks arising from toxin, produced in GM plants are covered by Annex A(1)(b).

7.2677 Moreover, in Section VII.C we indicated our view that if a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms, even if the non-target organisms do not eat the GM plant, *e.g.* through exposure other than through ingestion of food (such as contact with the leaves of a GM plant), the GM plant could be considered a "pest" within the meaning of Annex A(1)(a). Thus, a measure applied to protect from risks arising from such exposure to GM plants would, in our view, fall within the scope of Annex A(1)(a).

7.2678 In addition, in Section VII.C we concluded that to the extent that GM plants may result in changes in animal or plant populations, this may increase or decrease the food available for particular non-target animal populations and thus alter the fitness and health of these animal populations, which may in turn lead to further deleterious effects on the life or health of animals or other plants. We also recall our conclusion that by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a). Furthermore, we found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as insecticidal traits) resulting from transfer of genetic material from a GM plant.

7.2679 In view of the above findings, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential adverse effects on non-target organisms of MON810 maize, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

*Development of resistance to Bt toxin in insects, including indirect and long-term effects of insect resistance*

7.2680 We turn now to Austria's stated concern regarding the potential development of resistance to Bt toxin in insects associated with MON810 maize. We understand the concern identified by Austria to be that resistance in insects to Bt toxin may develop due to frequent exposure to this pesticide (the Bt toxin) and that the development of high levels of resistance in insect populations might require the application of a pesticide where none was used before, the increased application of a pesticide, or the application of more harmful pesticides to control the resistant populations.

7.2681 We recall our analysis in Section VII.C regarding the development of pesticide-resistance in insects. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We found that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2682 In view of the above findings, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential risks associated with the development of resistance to Bt toxin in insects due to the cultivation of MON810 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Allergenicity and toxicity*

7.2683 We turn now to Austria's stated concern regarding the potential risks of allergenicity and toxicity associated with MON810 maize. We recall our analysis related to allergens and toxins in Section VII.C and our analysis of this concern related to Austria's safeguard measures on T25 maize and Bt-176 maize.

7.2684 In particular, we recall that in Section VII.C we have found that to the extent a measure seeks to protect humans and animals from allergenic effects of GM plants used as or in foods, that measure can be considered to be a measure applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs and, as such, would fall within the scope of Annex A(1)(b). We furthermore recall our view that if interaction with, and exposure to, GMOs other than as or in a food produced allergenic effects in persons, the GMOs in question could be considered "pests" within the meaning of Annex A(1)(c).

7.2685 Consistent with our reasoning above, in the context of the case before us, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential allergenic or toxic effects of MON810 maize, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

*Development of antibiotic resistance*

7.2686 We turn finally to Austria's stated concern regarding the presence in MON810 maize of an antibiotic resistance marker gene (ARMG) and the possible development of antibiotic resistance. We understand this to be a concern about a potential transfer of the ARMG present in MON810 maize to bacteria of the intestine of humans or animals due to consumption of MON810 maize. We recall our discussion in Section VII.C regarding ARMG, and in particular our view that this concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2687 In Section VII.C we have found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2688 Thus, in view of our findings above, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential risks associated with the presence in MON810 maize of an ARMG, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

*Co-existence*

7.2689 We now turn to Austria's stated concern about co-existence. We understand this to be a concern that farmers cultivating conventional maize might experience a loss of economic value of their crop due to the existence of unwanted genetically modified maize plants in their fields (contamination). The loss would result from the circumstance that the farmers might no longer be able to market their crops as non-GM crops.

7.2690 In Section VII.C we have found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". Such plants include cross-breeds between GM maize and conventional maize which grow in a conventional maize field as a result of pollen dispersal. Such plants further include GM maize plants growing in a conventional maize field as a result of unintentional dispersal of GM seed. Thus, we consider that to the extent Austria's safeguard measure on MON810 maize is applied to prevent economic damage resulting from the contamination of conventional maize due to the entry, establishment or spread of MON810 maize (via dispersal of GM seed), or of cross-breeds between MON810 maize and conventional maize (via dispersal of GM pollen), in cultivated conventional maize fields, it falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

7.2691 In view of the above findings, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to prevent or limit damage from the possible contamination of conventional maize by MON810, falls within the scope of Annex A(1)(d) of the *SPS Agreement*.

*Conclusion with regard to the purpose of the safeguard measure*

7.2692 In the light of the above considerations, we conclude that the safeguard measure applied by Austria with respect to MON810 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2693 We now turn to the issue of the form and nature of Austria's safeguard measure on MON810 maize.

7.2694 We note that the arguments presented by the United States and Argentina regarding the form and nature of Austria's safeguard measure on MON810 maize are the same as for Austria's safeguard measure on T25 maize.

7.2695 Thus, as in the case of Austria's safeguard measure on T25 maize we conclude that the safeguard measure applied by Austria with respect to MON810 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2696 We have now considered Austria's safeguard measure on MON810 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Austria's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure taken by Austria with respect to MON810 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2697 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Austrian safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Austrian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Austrian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2698 We now turn to the issue of whether Austria's safeguard measure on MON810 maize is a measure that may affect international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Austria's safeguard measure on MON810 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2699 The **United States** argues that the measure adopted by Austria prohibits the "placing on the market" of MON810 maize, thereby effectively blocking the importation of the product.

7.2700 **Argentina** notes that since the safeguard measure prevents access of MON810 maize to Austria, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2701 The **Panel** notes that the arguments of the parties regarding the effects on trade of Austria's safeguard measure on MON810 maize are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. In view of the fact that Austria's safeguard measure prohibits imports of MON810 maize, we have no difficulty concluding that the safeguard measure by Austria is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2702 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Austrian safeguard measure on MON810 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Austrian safeguard measure on MON810 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(v) France – MS1/RF1 oilseed rape (EC-161)*

7.2703 We now turn to the safeguard measure applied by France on MS1/RF1 oilseed rape (EC-161). We recall that the application for placing on the market, growing and obtaining seeds of this oilseed rape was initially submitted to the United Kingdom.[1736] The product was authorized by the Commission in February 1996 for cultivation and placing on the market.[1737] In November 1998, France adopted a Decree suspending commercialization of MS1/RF1 oilseed rape (EC-161) on its territory for a period of two years.[1738] The period of application of the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was extended twice, namely in July 2001[1739] and July 2003.[1740]

Is the French safeguard measure on MS1/RF1 oilseed rape (EC-161) an SPS measure?

7.2704 We start with the issue of whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2705 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2706 The **United States** notes that according to the SCP, France justified the ban based on its "concern over the environmental impact of genetic escape" and the "spread of herbicide tolerance" to other plants. This justification indicates that the French measures are sanitary and phytosanitary measures as they are applied "to protect [...] plant life or health" from the "spread of pests" and "prevent or limit other damage" from the "spread of pests".

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[1736] C/UK/94/M1/1.

[1737] Commission Decision 96/158, 6 February 1996.

[1738] France, Ministry of Agriculture and Fishing, Decree of 16 November 1998 involving suspension of the commercialisation of genetically modified colza by virtue of Article 16 of Directive 90/220/European Communities of 23 April 1990, pursuant to Decision 96/158 of 6 February 1996, Official Journal, No. 267, 18 November 1998, at 17379 (Exhibits US-60; CDA-68).

[1739] France, Ministry of Agriculture and Fishing, Decree of 26 July 2001 regarding suspension of the sale of genetically modified colza by virtue of Article 16 of Directive 90/220/European Communities of 23 April 1990, pursuant to Decision 96/158/European Communities of 6 February 1996, Official Journal, 30 August 2001 at 13903 (Exhibit CDA-70).

[1740] France, Ministry of Agriculture, Food, Fisheries and Rural Affairs, Order of 25 July 2003 suspending the marketing of genetically modified rapeseed pursuant to Article 23 of Directive 2001/18/European Communities of 12 March 2001, Official Journal, 14 August 2003 at 14061 (Exhibit CDA-71).

7.2707 **Canada** notes that the French safeguard measure against MS1/RF1 oilseed rape (EC-161) is predicated on concerns that its release into the environment may have detrimental effects on the surrounding plant life or health. More specifically, France indicated that it was concerned about genetic escape from the biotech varieties, leading to the transfer of herbicide resistance through hybridization with wild oilseed rape varieties. In essence, the concerns of France were related to potential risks arising from the release into the environment of the biotech oilseed rape varieties because of their alleged potential to function as a pest in relation to the surrounding environment, and in particular, to out-cross with wild species of oilseed rape.

7.2708 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects of management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2709 In examining the purposes for which France's measure on MS1/RF1 oilseed rape (EC-161) is applied, the **Panel** will first consider the document notified by France to the Commission in November 1998 which sets out the reasons for suspending the placing on the market of MS1/RF1 oilseed rape (EC-161) for an initial period of two years (hereafter the "Reasons document").[1741]

7.2710 In the Reasons document, France justifies its safeguard measure on MS1/RF1 oilseed rape (EC-161) on the basis of alleged risks to the environment. In particular, France was concerned with the potential dissemination of the herbicide-tolerance gene into the environment through hybridisation with other plant species, as well as among different varieties of oilseed rape. France notes that while experimental platforms have been set up to measure and quantify on an agronomic scale the extent and consequences of gene flows in various species, including oilseed rape, knowledge in this area is still fragmented. It further notes that the agricultural practices at issue must be considered in the broader context of their global impact on the environment.

7.2711 We note that France's decision to extend the application of its safeguard measure suspending the placing on the market of MS1/RF1 oilseed rape (EC-161) in July 2001[1742] and July 2003[1743] was based on opinions from the French "Commission du Génie biomoléculaire" (hereafter the "Biomolecular Engineering Committee" or "BEC"), delivered in February 2001[1744] and July 2003[1745] respectively, at the request of the French authorities. In its February 2001 opinion, the BEC invokes the need to pursue scientific experiments with a view to complete current scientific knowledge and to validate risk management options for the cultivation of GM oilseed rape that could limit potential adverse effects on the environment. In particular, the BEC opinion points to the need to obtain additional information on the effects of pollen dispersal from oilseed rape plants and the role of

[1741] The document entitled "*Motivation du moratoire, pour une période de deux ans, relative à la mise en marché sur le territoire français de colza génétiquement modifié tolérant aux herbicides, en application de l'Article 16 de la Directive 90/220/EEC: Nouveaux éléments en matière d'évaluation du risque pour l'environnement*" sets out the reasons for France's safeguard measures on MS1/RF1 oilseed rape and Topas oilseed rape (Exhibits EC-161/At. 2 and EC-162/At. 5).

[1742] The Panel notes that this decision adopted by France on 26 July 2001 to suspend the placing on the market of MS1/RF1 for a period of two years, was not submitted to the Panel.

[1743] The safeguard measure was renewed on the basis of Article 23 of Directive 2001/18 (Exhibits EC-161/At. 3 and EC-161/At. 5).

[1744] It is not clear to the Panel whether this opinion of the BEC was submitted as evidence by the European Communities. We note that the documents contained in Exhibits EC-161/At. 7 and EC-161/At. 8, which seem to be translations of the document contained in EC-161/At. 6, are not dated.

[1745] Exhibit EC-161/At. 9.

insects in its transport, as well as the effects of persistence of oilseed rape plants resulting from seed dispersal during transportation and pollenisation of neighbouring oilseed rape plants. The opinion further indicates that modalities for management are necessary in order to limit the direct and indirect effects of re-growth of oilseed rape in the case of herbicide tolerance, and that large scale experiments are necessary in order to validate such modalities.

7.2712 In its July 2003 opinion, the BEC pointed to the existence of new elements of information, including, *inter alia*, with respect to the issues of pollen dispersal, characterization of inter-specific hybrids and re-growth. The BEC considered that these new elements of information required further analysis in order to determine whether they put into question the conclusions of the February 2001 opinion, on which the decision to maintain the safeguard measure on MS1/RF1oilseed rape (EC-161) was based.[1746] To this end, the BEC recommended the organization of a scientific workshop to take stock of ongoing research and to eventually identify modalities for the management of genetically modified oilseed rape. [1747]

7.2713 We note that France further elaborated on its concerns with respect to MS1/RF1 oilseed rape (EC-161) in a Note addressed to the Commission in July 2003 regarding the extension of the safeguard measure. In this Note, France recalls that the decision to apply a safeguard measure on MS1/RF1 oilseed rape (EC-161) is based on the potential risk of contamination of conventional oilseed rape by genetically modified oilseed rape.[1748]

7.2714 A further informal Note was provided by France to the Commission after the establishment of the Panel.[1749] The Note recalls the concerns underlying, *inter alia*, the safeguard measure on MS1/RF1 oilseed rape (EC-161) , including those relating to the environmental consequences of gene transfer to other plants and the economic consequences of contamination (co-existence issue). The Note indicates that the BEC was to hold a scientific workshop in November 2003 and that the safeguard measure on MS1/RF1 oilseed rape (EC-161) might be withdrawn if after the workshop the BEC provided favourable scientific advice on the outstanding concerns. Looking ahead, the Note concludes that the maintenance of the safeguard measure at issue was justified at the time by the precautionary principle, pending a clearer and more complete scientific picture. The Note goes on to state, however, that the safeguard measure would in any event not be withdrawn before the entry into force of the new EC regulations on labelling and traceability as well as on GM food and feed.

7.2715 Finally, we note that the BEC delivered an opinion in February 2004 based on the conclusions of a scientific workshop held in November 2003.[1750] The opinion concludes that the cultivation of MS1/RF1 oilseed rape (EC-161) does not present any direct risk for the environment, but that modalities are nonetheless required to manage indirect ecological risks, which are related to practices associated with the cultivation of MS1/RF1 oilseed rape (EC-161).

7.2716 Based on the foregoing, we consider that at the time of review by the Panel, France applied its safeguard measure to address concerns about:

(1) transfer of the herbicide-tolerance gene to adventitious flora;

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[1746] Exhibit EC-161/At. 9. *See also* Exhibit EC-161/At. 5.

[1747] *Ibid.*

[1748] Exhibit EC-161/At. 3.

[1749] Exhibit EC-161/At. 4. While the document is not dated, we note that it makes reference to the proceedings before this Panel, thus suggesting that the document was circulated after the establishment of the Panel.

[1750] Exhibit EC-161/At. 10.

(2) adverse effects on the environment, including from persistence and management practices associated with the cultivation of MS1/RF1 oilseed rape (EC-161); and
(3) contamination of conventional oilseed rape by genetically modified oilseed rape.

7.2717 The European Communities asserts that France's safeguard measure on MS1/RF1 oilseed rape (EC-161) is also applied in view of concerns about labelling, but provides no substantiation or explanation of this assertion. The labelling concern asserted by the European Communities was not articulated by France in any of the documents discussed by us above which date from before the date of establishment of this Panel. However, as we have pointed out, after the establishment of the Panel, France in an informal Note to the Commission made reference to the new EC regulation on labelling and traceability as well as to the new EC regulation on GM food and feed. These regulations contain new labelling requirements. Nevertheless, for the reasons which follow, we are not persuaded that it can be inferred from this post-2003 reference to labelling that France in August 2003 applied its safeguard measure on MS1/RF1 oilseed rape (EC-161) to address concerns about labelling.

7.2718 To begin with, we recall that according to the Note the relevant safeguard measure is justified by the precautionary principle, pending a clearer and more complete scientific picture. Insufficient labelling is not claimed as a separate justification. Indeed, the Note indicates that in July 2003 France extended its safeguard measure for one year on the basis of scientific advice received from the BEC in July 2003. Moreover, the reference to labelling is made in a forward-looking context, *i.e.*, in the context of a discussion of the "way ahead".[1751] It is clear from the Note that France at the time was waiting for further advice from the BEC (in the wake of the November 2003 scientific workshop to be held by the BEC) which it said could lead to the withdrawal of the safeguard measure if the outstanding concerns were satisfactorily addressed by the BEC. The Note states, however, that even if the BEC were to offer favourable scientific advice, France would not withdraw its safeguard measure prior to the entry into force of the new EC regulations. We consider that it may be appropriate to infer from this statement that in case of favourable advice from the BEC following the November 2003 workshop, concerns about labelling would be the reason for maintaining the safeguard measure.[1752] But we do not think that it may be properly inferred from this forward-looking statement that concerns about labelling were a reason for applying the relevant safeguard measure in August 2003, when France was still waiting for the results of the November 2003 scientific workshop and subsequent scientific advice from the BEC. In the light of this, as indicated, we are not persuaded that France at the time of review by the Panel was applying its safeguard measure to address concerns about labelling as asserted by the European Communities.

7.2719 Having determined the purposes for which France applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of France's safeguard measure.

*Transfer of the herbicide-tolerance gene to adventitious flora*

7.2720 We turn first to France's stated objective for prohibiting the placing on the market of MS1/RF1 oilseed rape (EC-161) due to concerns over the transfer of the herbicide-tolerance gene contained in MS1/RF1 oilseed rape (EC-161) to adventitious flora. We understand this to be essentially a concern about the potential environmental impacts associated with gene transfer from

[1751] The Note uses the French word "perspectives".
[1752] We note in this context that the Note in question is an informal note which bears no official letterhead nor a date or signature which would allow us to confirm that the views expressed in the Note are attributable to, and expressed on behalf of, France.

MS1/RF1 oilseed rape (EC-161) to adventitious flora, and in particular about the environmental impacts of the possible development of herbicide resistant weeds.

7.2721 We recall our finding in Section VII.C that cross-breeds between conventional and GM plants could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide resistance) and harm animal or plant life or health or result in other damage. We have determined on that basis that measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) from the entry, establishment or spread of cross-breeds with undesired traits resulting from the transfer of genetic material from a GM plant fall within the scope of Annex A(1)(a), while measures applied to prevent "other damage" to the environment from the entry, establishment or spread of cross-breeds fall within the scope of Annex A(1)(d).

7.2722 In addition, we recall that one possible concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or different, more toxic herbicides, to control the resistant weeds. We determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We deduced from this that measures applied to avoid such indirect adverse effects on the environment fall within the scope of Annex A(1)(a) and (d).

7.2723 Consistent with our reasoning above, we consider that France's safeguard measure on MS1/RF1 oilseed rape (EC-161), to the extent it is applied to avoid risks to the environment associated with the transfer of the herbicide-tolerance gene contained in MS1/RF1 oilseed rape (EC-161) to adventitious flora, and in particular the development of resistance in weeds, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

> *Adverse effects on the environment, including from persistence and management practices associated with the cultivation of MS1/RF1 oilseed rape*

7.2724 We turn now to the next objective stated by France for prohibiting the placing on the market of MS1/RF1 oilseed rape (EC-161), namely, France's concerns over potential adverse effects on the environment, including the environmental effects of persistence resulting from seed dispersal during transportation and of management techniques associated with the cultivation of MS1/RF1 oilseed rape (EC-161).

7.2725 In Section VII.C we have found that to the extent a measure is applied to avoid adverse effects on plant life or health that might arise if GM plants crowd out or eliminate other plants due to a potential competitive advantage, invasiveness or persistence, such a measure would be covered by Annex A(1)(a), as it would be applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

7.2726 In Section VII.C we also found that to the extent that GM plants may result in changes in plant populations, this may increase or decrease the food available for particular animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce. We state that, by causing harm to the health of animals or other plants in this way, the GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a).

7.2727 Moreover, we stated that to the extent a measure is applied to avoid adverse effects on the life or health of animals or plants which arise from particular management (weed control) practices associated with GMOs, such a measure falls within the scope of Annex A(1)(a), in that it can be viewed as a measure applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".

7.2728 Finally, we found that to the extent a measure seeks to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health, such a measure can be considered to be covered by Annex A(1)(d), inasmuch as it can be viewed as a measure which is applied to prevent or limit "other damage" from the entry, establishment or spread of "pests". As noted earlier, the GMOs themselves might qualify as the relevant pest, or other plants or animals might become pests as a result of the release of GMOs into the environment. Furthermore, we said that to the extent that a measure is applied to avoid adverse environmental effects arising from management (weed control) practices associated with GMOs other than damage to the life or health of animals or plants, that measure can be considered as a measure applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests" and would thus also be covered by Annex A(1)(d).

7.2729 Consistent with our reasoning above, we consider that France's safeguard measure on MS1/RF1 oilseed rape (EC-161), to the extent it is applied to avoid adverse effects on the environment, including from management practices associated with the cultivation of MS1/RF1 oilseed rape (EC-161), falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Contamination of conventional oilseed rape by genetically modified oilseed rape*

7.2730 We finally address France's concern with regard to the risk of contamination of conventional oilseed rape by genetically modified oilseed rape, *i.e.*, MS1/RF1 oilseed rape (EC-161).

7.2731 We have already addressed France's concern about the possible transfer of the introduced herbicide-tolerance gene from MS1/RF1 oilseed rape to adventitious flora, which includes gene transfer from MS1/RF1 oilseed rape to different species (resulting in inter-specific hybrids), but also includes gene transfer to wild or cultivated conventional oilseed rape. Thus, for the reasons which we have outlined above, we consider that to the extent France's safeguard measure on MS1/RF1 oilseed rape is applied to avoid adverse environmental effects arising from the contamination of conventional oilseed rape by MS1/RF1 oilseed rape due to gene transfer from MS1/RF1 oilseed rape to conventional oilseed rape, it falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2732 In our understanding, France's concern about contamination of conventional oilseed rape is also a concern that farmers cultivating conventional oilseed rape might experience a loss of economic value of their crop due to the existence of unwanted genetically modified oilseed rape plants in their fields. The loss would result from the circumstance that the farmers might no longer be able to market their crops as non-GM crops. Even if France's concern about contamination were understood in this way, however, France's safeguard measure would, in our view, fall within the scope of Annex A(1) of the *SPS Agreement*.

7.2733 We recall in this regard that in Section VII.C we found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". Such plants include cross-breeds between GM oilseed rape and conventional oilseed rape which grow in a

conventional oilseed rape field as a result of pollen dispersal. Such plants further include GM oilseed rape plants growing in a conventional oilseed rape field as a result of unintentional dispersal of GM seed. Thus, we consider that to the extent France's safeguard measure on MS1/RF1 oilseed rape (EC-161) is applied to prevent economic damage resulting from the contamination of conventional oilseed rape due to the entry, establishment or spread of MS1/RF1 oilseed rape (via dispersal of GM seed), or of cross-breeds between MS1/RF1 oilseed rape and conventional oilseed rape (via dispersal of GM pollen), in cultivated conventional oilseed rape fields, it falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

7.2734 In view of the above findings, we consider that France's safeguard measure on MS1/RF1 oilseed rape (EC-161), to the extent it is applied to avoid adverse effects arising from the possible contamination of conventional oilseed rape by MS1/RF1 oilseed rape (EC-161), falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Conclusion with regard to the purpose of the safeguard measure*

7.2735 In the light of the above considerations, we conclude that the safeguard measure applied by France with respect to MS1/RF1 oilseed rape (EC-161) qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2736 We now turn to the issue of form and nature of France's safeguard measure on MS1/RF1 oilseed rape (EC-161). We start by recalling the Parties' arguments on this matter.

7.2737 The **United States** argues that the measure is in the form of a "decree" from the French Minister of Agriculture and Fishing, which is among the types of measures explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2738 **Canada** argues that the French measure is in the form of a "decree", one of the types of measures expressly enumerated in Annex A(1) of the *SPS Agreement*.

7.2739 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms.[1753] Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2740 We note that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was implemented through a decree to prohibit commercialisation of MS1/RF1 oilseed rape (EC-161). Annex A(1) specifically refers to "decrees". We therefore consider that, for the purposes of Annex A(1), the French decree is an SPS measure in respect of the form of the measure.

7.2741 In respect of the nature of the French measure, we note that the decree prohibits the marketing of MS1/RF1 oilseed rape (EC-161). As indicated above, we are of the view that a prohibition on the

[1753] *See supra*, para. 7.1334.

marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2742 We therefore conclude that the safeguard measure taken by France with respect to MS1/RF1 oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2743 We have now considered France's safeguard measure on MS1/RF1 oilseed rape (EC-161) in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that France's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by France with respect to MS1/RF1 oilseed rape (EC-161) constitutes an "SPS measure" within the meaning of Annex A(1).

7.2744 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the French safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Canada or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the French safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the French safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2745 We now turn to the issue of whether France's safeguard measure on MS1/RF1 oilseed rape (EC-161) is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for France's safeguard measure on MS1/RF1 oilseed rape (EC-161) to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2746 The **United States** argues that the measure adopted by France prohibits the "placing on the market" of MS1/RF1 oilseed rape (EC-161), thereby effectively blocking the importation of the product.

7.2747 **Canada** argues that the measure suspends commercialization of MS1/RF1 oilseed rape (EC-161), as well as prohibiting its importation on the French territory. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2748 The **Panel** notes that the arguments of the parties regarding the effects on trade of France's safeguard measure on MS1/RF1 oilseed rape (EC-161) are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that France's safeguard measure prohibits imports of MS1/RF1 oilseed rape (EC-161), we have no difficulty concluding that the safeguard measure applied by France is an SPS measure

which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2749 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(vi) France – Topas oilseed rape*

7.2750 We now turn to the safeguard measure applied by France on Topas oilseed rape. We recall that the application for placing on the market, growing and obtaining seeds of this oilseed rape was initially submitted to the United Kingdom.[1754] The product was authorized by the European Commission in April 1998.[1755] In November 1998, France adopted a Decree suspending the placing on the market of Topas oilseed rape for a period of two years.[1756] This Decision, which was taken on the basis of Article 16 of Directive 90/220, was notified to the Commission in May 1999. The period of application of the French safeguard measure on Topas oilseed rape was extended twice, namely in July 2001[1757] and July 2003.[1758]

Is the French safeguard measure on Topas oilseed rape an SPS measure?

7.2751 We start with the issue of whether the French safeguard measure on Topas oilseed rape is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

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[1754] C/UK/95/M5/1.

[1755] Commission Decision 98/291, April 1998.

[1756] France, Ministry of Agriculture and Fishing, Decree of 16 November 1998 involving suspension of the commercialization of genetically modified colza by virtue of Article 16 of Directive 90/220 of 23 April 1990, pursuant to Decision 98/291 of 22 April 1998, Official Journal, 18 November 1998, at 17379 (Exhibit CDA-64).

[1757] France, Ministry of Agriculture and Fishing, Decree of 26 July 2001 regarding suspension of the sale of genetically modified colza by virtue of Article 16 of Directive 90/220/European Communities of 23 April 1990, pursuant to Decision 96/158/European Communities of 6 February 1996, Official Journal, 30 August 2001 at 13903 (Exhibit CDA-70).

[1758] France, Ministry of Agriculture, Food, Fisheries and Rural Affairs, Order of 25 July 2003 suspending the marketing of genetically modified rapeseed pursuant to Article 23 of Directive 2001/18/European Communities of 12 March 2001, Official Journal, 14 August 2003 at 14061 (Exhibit CDA-71).

Purpose of the safeguard measure

7.2752 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2753 The **United States** notes that according to the SCP, France justified the ban based on its "concern over the environmental impact of genetic escape" and the "spread of herbicide tolerance" to other plants. This justification indicates that the French measures are sanitary and phytosanitary measures as they are applied "to protect [...] plant life or health" from the "spread of pests" and "prevent or limit other damage" from the "spread of pests".

7.2754 **Canada** notes that the French safeguard measure against Topas oilseed rape is predicated on concerns that its release into the environment may have detrimental effects on the surrounding plant life or health. More specifically, France indicated that it was concerned about genetic escape from the biotech varieties, leading to the transfer of herbicide resistance through hybridization with wild oilseed rape varieties. In essence, the concerns of France were related to potential risks arising from the release into the environment of the biotech oilseed rape varieties because of their alleged potential to function as a pest in relation to the surrounding environment, and in particular, related wild species of oilseed rape.

7.2755 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2756 The **Panel** observes that the French decisions to suspend the placing on the market of Topas oilseed rape identify exactly the same purposes for this safeguard measure at the time of review by the Panel as those invoked by France with respect to its safeguard measure on MS1/RF1 oilseed rape.[1759] Thus, based on the relevant information provided by the Parties, we consider that at the time of review by the Panel, France applied its safeguard measure on Topas oilseed rape to address concerns about:

(1) transfer of the herbicide-tolerance gene to adventitious flora;
(2) adverse effects on the environment, including from persistence; and
(3) contamination of conventional oilseed rape by genetically modified oilseed rape.

7.2757 The European Communities asserts that France's safeguard measure on Topas oilseed rape is also applied in view of concerns about labelling, but provides no substantiation or explanation of this assertion. The labelling concern asserted by the European Communities was not articulated by France in any of the relevant documents which date from before the date of establishment of this Panel. However, after the establishment of the Panel, France in an informal Note to the Commission made reference to the new EC regulation on labelling and traceability as well as to the new EC regulation on GM food and feed.[1760] We have already examined this document in the context of our analysis of the French safeguard measure on MS1/RF1 oilseed rape. Since the document also concerns the French safeguard measure on Topas oilseed rape, our earlier analysis is applicable to the safeguard

[1759] We note, however, that unlike MS1/RF1 oilseed rape, Topas oilseed rape was not approved for cultivation. It was approved for import, storage and processing.

[1760] Exhibit EC-161/At. 4.

measure on Topas oilseed rape as well. Thus, for the reasons we have outlined earlier in paragraph 7.2718, we are not persuaded that it can be inferred from the post-2003 reference to labelling in the French Note that France in August 2003 applied its safeguard measure on Topas oilseed rape to address concerns about labelling.

7.2758 Having determined the purposes for which France applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of France's safeguard measure.

*Transfer of the herbicide-tolerance gene to adventitious flora*

7.2759 Considering first France's stated objective for prohibiting the placing on the market of Topas oilseed rape due to concerns over the transfer of the herbicide-tolerance gene contained in Topas oilseed rape to adventitious flora, we recall our analysis of this concern in the context of our discussion of France's safeguard measure on MS1/RF1 oilseed rape.

7.2760 Consistent with our reasoning there, we consider that France's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid risks associated with the transfer of the herbicide-tolerance gene contained in Topas oilseed rape to adventitious flora, and in particular the development of resistance in weeds due to cultivation of Topas oilseed rape, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Adverse effects on the environment, including from persistence*

7.2761 We turn now to the next objective stated by France for prohibiting the placing on the market of Topas oilseed rape, namely, France's concerns over potential adverse effects on the environment, including the environmental effects of persistence resulting from seed dispersal during transportation.[1761] We recall our analysis of this concern in the context of our discussion of France's safeguard measure on MS1/RF1 oilseed rape.

7.2762 Consistent with our reasoning there, we consider that France's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid adverse effects on the environment, including from persistence, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Contamination of conventional oilseed rape by genetically modified oilseed rape*

7.2763 We address finally France's concern with regard to the risk of contamination of conventional oilseed rape by genetically modified oilseed rape. We recall in this regard our analysis of this concern in the context of our discussion of France's safeguard measure on MS1/RF1 oilseed rape.

7.2764 Consistent with our reasoning there, we consider that France's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid adverse environmental or economic effects arising from the possible contamination of conventional oilseed rape by Topas oilseed rape, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

[1761] Since Topas oilseed rape was not approved for cultivation, our analysis in the context of MS1/RF1 oilseed rape relating to the adverse environmental effects resulting from management practices associated with the cultivation of MS1/RF1 oilseed rape is not applicable here.

*Conclusion with regard to the purpose of the safeguard measure*

7.2765 In the light of the above considerations, we therefore conclude that the safeguard measure applied by France with respect to Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2766 We now turn to the issue of the form and nature of France's safeguard measure on Topas oilseed rape. We note that the Parties have made the same arguments with respect to France's safeguard measure on Topas oilseed rape as for France's safeguard measure on MS1/RF1 oilseed rape (EC-161).

7.2767 Consistent with our analysis with respect to France's safeguard measure on MS1/RF1 oilseed rape (EC-161), we conclude that France's safeguard measure on Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2768 We have now considered France's safeguard measure on Topas oilseed rape in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that France's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by France with respect to Topas oilseed rape constitutes an "SPS measure" within the meaning of Annex A(1).

7.2769 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the French safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Canada or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the French safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the French safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2770 We now turn to the issue of whether France's safeguard measure on Topas oilseed rape is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for France's safeguard measure on Topas oilseed rape to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2771 The **United States** argues that the measure adopted by France prohibits the "placing on the market" of Topas oilseed rape, thereby effectively blocking the importation of the product.

7.2772 **Canada** argues that the measure suspends commercialization of Topas oilseed rape, and prohibits its importation on the French territory. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2773 The **Panel** notes that the arguments of the parties regarding the effects on trade of France's safeguard measure on Topas oilseed rape are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that France's safeguard measure prohibits imports of Topas oilseed rape, we have no difficulty concluding that the safeguard measure applied by France is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2774 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the French safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the French safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(vii) Germany – Bt-176 maize*

7.2775 We now turn to the safeguard measure applied by Germany on Bt-176 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1762] The product was authorized by the European Commission in 1996.[1763] Germany informed the Commission of its decision to restrict the authorization for the placing on the market of Bt-176 maize in a letter dated 2 March 2000.[1764] Germany amended its original decision on Bt-176 maize by a further decision adopted on 31 March 2000.[1765] This amended decision suspends the placing on the market of Bt-176 maize and its progeny in Germany, unless cultivation is intended for research and

[1762] C/F/94/11-03.
[1763] Commission Decision 97/98 (Exhibits US-97; ARG-37).
[1764] The letter is from the Robert Koch Institute (Exhibit EC-158/At. 19_trans).
[1765] Exhibits US-65; ARG-13.

testing purposes in certain specified areas.[1766] This decision was notified to the Commission in April 2000.[1767]

Is the German safeguard measure on Bt-176 maize an SPS measure?

7.2776 We start with the issue of whether Germany's safeguard measure on Bt-176 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2777 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2778 The **United States** notes that the concerns expressed by Germany with regard to Bt-176 maize include the effect of Bt toxin on non-target organisms, the development of insect resistance to Bt toxin, and the transfer of antibiotic resistant genes to humans and animals. On the basis of these justifications, the United States argues that the German safeguard measure is an SPS measure, as it is applied to "protect animal life or health" from "disease-causing organisms"; or "protect human life or health" from "toxins" or "disease-causing organisms in foods"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2779 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2780 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2781 The **Panel** notes that Germany sets out its reasons for adopting the safeguard measure on Bt-176 maize in a letter to the Commission dated 4 April 2000.[1768] In this document, Germany refers to recent laboratory investigations and relevant studies with insect species which suggest that the ingestion of pollen from maize plants expressing Bt-toxin may produce harmful effects in non-target

[1766] The prohibition did not apply in the case of cultivation intended for research and testing purposes in the following areas: effects on target or non-target organisms, the development of resistance, counter measures to resistance development, horizontal or vertical gene transfer, ecological assessments or the enhancement of agronomic and plant protection knowledge for practical application.

[1767] The amended decision was notified to the Commission on 4 April 2000 (Exhibit EC-158/At. 21), and again on 28 April 2000 with the relevant scientific evidence considered by Germany in the context of the adoption of its safeguard measure (Exhibits EC-158/At. 23-29).

[1768] Exhibit EC-158/At. 21. The Panel notes that the concerns of Germany with respect to Bt-176 maize are also outlined in the letter of 31 March 2000 (Exhibit US-65).

insects through their absorption of the Bt-toxin.[1769] Germany notes that in the case of unrestricted cultivation, resistance to Bt toxin may develop in maize pests and non-target organisms, thereby impeding the applicability of Bt toxin as a pesticide. Other studies reported that Bt toxin enters the soil from the roots of genetically modified maize plants. Germany submits that these studies suggest that if cultivation is unrestricted, the presence of Bt toxin could have adverse effects on living organisms in the soil. Finally, Germany notes that the cultivation of a transgenic variety with antibiotic-resistant genes might increase the development of antibiotic resistance following the ingestion of the gene by humans and animals.

7.2782 Based on the foregoing, we consider that at the time of review by the Panel, Germany applied its safeguard measure on Bt-176 maize to address concerns about:

(1) effects on non-target organisms;
(2) the development of resistance to Bt toxin in insects;
(3) possible adverse effects of the Bt toxin in the soil; and
(4) the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans and animals.

7.2783 The European Communities asserts that Germany's safeguard measure on Bt-176 maize is also applied in view of concerns about labelling and co-existence. These asserted concerns were not articulated by Germany in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Germany is applying its safeguard measure to address these additional concerns identified by the European Communities.

7.2784 Having determined the purposes for which Germany applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Germany's safeguard measure.

*Effects on non-target organisms*

7.2785 We begin our analysis with the purpose of managing potential risks associated with effects on non-target organisms.

7.2786 We refer to our conclusions in Section VII.C that a GM crop that is eaten by animals can be considered to be a "food" for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. As we previously noted, a poisonous substance, such as the Bt toxin, which is produced by a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b).[1770] We determined on that basis that measures applied to protect the life or health of animals (not including target organisms) from risks arising from toxins produced in GM plants are covered by Annex A(1)(b).

7.2787 Moreover, we indicate in Section VII.C our view that if a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms, even if the non-target organisms do not eat the GM plant, *e.g.* through exposure other than through ingestion of food, the GM plant could be considered a "pest" within the meaning of Annex A(1)(a). Thus, a measure

[1769] It is noted, however, that adverse effects are not expected in respect of the specified cultivation purposes if the quantity sown is limited to 12 tonnes per year in a cultivation area limited to 500 hectares.

[1770] We recall our view that the term "toxin" as it appears in Annex A(1)(b) includes allergens.

applied to protect from risks arising from such exposure to GM plants would, in our view, fall within the scope of Annex A(1)(a).

7.2788 In addition, in Section VII.C we conclude that to the extent that GM plants may result in changes in animal or plant populations, this may increase or decrease the food available for particular non-target animal populations and thus alter the fitness and health of these animal populations, which may in turn lead to further deleterious effects on the life or health of animals or other plants. We also recall our conclusion that by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a). Furthermore, we found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as insecticidal traits) resulting from transfer of genetic material from a GM plant.

7.2789 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential risks to the health of non-target organisms from the consumption of Bt-176 maize, falls within the scope of Annex A(1)(b) of the *SPS Agreement*. Furthermore, to the extent that Germany's safeguard measure is applied to avoid other potential adverse effects on non-target organisms arising from Bt-176 maize, it falls within the scope of Annex A(1)(a) of the *SPS Agreement*.

*Development of resistance to Bt toxin in insects*

7.2790 Turning next to the concern regarding the development of resistance to Bt toxins in insects, we refer to our analysis of this type of concern in Section VII.C and in the context of our discussion of Austria's safeguard measure on Bt-176 maize above.

7.2791 We refer to our analysis in Section VII.C regarding the development of pesticide-resistance in target organisms. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We found that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2792 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to protect from risks associated with the development of resistance to Bt toxin in insects due to the cultivation of Bt-176 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Possible adverse effects of the Bt toxin in the soil*

7.2793 We turn next to Germany's concern related to the possible adverse effects of the Bt toxin in the soil. We understand Germany's concern to be about adverse effects on living organisms in the soil.

7.2794 In Section VII.C, we found that the phrase "animal and plant" in Annex A(1) covers also soil microfauna or –flora. In addition, we found that to the extent that GM plants might affect the life or health of non-target soil microfauna or –flora, they could be considered as "pests" in the sense of

Annex A(1). Thus, to the extent Germany's safeguard measure is applied to address concerns that Bt-176 maize might affect the life or health of non-target soil microfauna or –flora, it can, in our view, be considered to be a measure applied to protect the life or health of soil microfauna or –flora from risks arising from the entry, establishment or spread of a Bt-producing GM plant *qua* "pest" within the meaning of Annex A(1)(a) of the *SPS Agreement*.

7.2795 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks associated with adverse effects of the Bt toxin on living organisms in the soil, falls within the scope of Annex A(1)(a) of the *SPS Agreement*.

*Transfer of the bla-ampicillin resistance gene to bacteria of the intestine of humans or animals*

7.2796 We turn finally to Germany's stated concern regarding the potential transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of Bt-176 maize. With respect to the transfer of antibiotic resistance marker genes to the intestine of humans or animals, we note that the Parties' arguments are the same as those made in relation to Austria's safeguard measures on T25 maize and Bt-176 maize. We refer to our discussion in Section VII.C regarding ARMG. More particularly, we recall that, in our view, the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2797 In Section VII.C we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2798 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks associated with the transfer of the *bla*-ampicillin resistance gene from Bt-176 maize to bacteria in the intestine of humans or animals, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

*Conclusion with regard to the purpose of the safeguard measure*

7.2799 In the light of the above considerations, we conclude that the safeguard measure applied by Germany with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2800 We now turn to the issue of the form and nature of Germany's safeguard measure on Bt-176 maize. We start by recalling the arguments of the Parties on this matter.

7.2801 The **United States** argues that the measure was in the form of a "notice" from the government agency with responsibility for the regulation of biotech products. Through this "notice", the German Government "ordered" suspension of the approval for commercialization of Bt-176 maize on the German territory. The word "order" is defined as "an authoritative direction", which is similar to the definition of "regulation". A "regulation" is among the types of measures explicitly mentioned in Annex A(1).

7.2802 **Argentina** notes that the measure was implemented by means of an amendment notice suspending the entry of Bt-176 maize. The measure has the same binding nature as a law, regulation, order or requirement.

7.2803 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms.[1771] Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2804 We note that the German safeguard measure on Bt-176 maize was implemented through a decision by the Robert Koch Institute, the competent German authority, to prohibit commercialization of Bt-176 maize on the German territory. Annex A(1) does not specifically refer to "decisions". As we have pointed out, this fact alone does not necessarily mean that Germany's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Germany's decision clearly is a measure attributable to the German Government. It is also not in dispute that the decision is legally binding. We therefore consider that, for the purposes of Annex A(1), the German decision may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2805 In respect of the nature of the German measure, we note that the decision prohibits the marketing of Bt-176 maize. As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2806 We therefore conclude that the safeguard measure taken by Germany with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2807 We have now considered Germany's safeguard measure on Bt-176 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Germany's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by Germany with respect to Bt-176 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2808 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the German safeguard measure could be considered to embody more than one SPS measure.

[1771] *See supra*, footnote 1753.

However, neither the United States nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the German safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the German safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2809 We now turn to the issue of whether Germany's safeguard measure on Bt-176 maize is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Germany's safeguard measure on Bt-176 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2810 The **United States** argues that the measure adopted by Germany suspends the approval for commercialization of Bt-176 maize, thereby effectively blocking the importation of the product. The measure as such therefore affects international trade.

7.2811 **Argentina** notes that since the safeguard measure prevents access of Bt-176 maize to Germany, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2812 The **Panel** notes that the arguments of the parties regarding the effects on trade of Germany's safeguard measure on Bt-176 maize are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that Germany's safeguard measure prohibits imports of Bt-176 maize, we have no difficulty concluding that the safeguard measure applied by Germany is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2813 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the German safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the German safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(viii) Greece – Topas oilseed rape*

7.2814 We now turn to the safeguard measure applied by Greece with respect to Topas oilseed rape. We recall that the application for placing on the market of this product was initially submitted to the United Kingdom.[1772] The product was approved for import and processing by the European Commission in April 1998[1773], and Greece adopted its safeguard measure to prohibit imports of Topas oilseed rape pursuant to Article 16 of Directive 90/220 in September 1998.[1774]

Is the Greek safeguard measure on Topas oilseed rape an SPS measure?

7.2815 We start with the issue of whether the Greek safeguard measure on Topas oilseed rape is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2816 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A (1) of the *SPS Agreement*.

7.2817 The **United States** notes that according to the SCP, Greece justified its safeguard measure on the basis of its concern for "genetic escape" and the consequences it could have on agriculture, the natural environment of Greece and consumer health. Concerns regarding "genetic escape" relate to adverse effects from the transfer of the herbicide tolerant gene to other plants or to consuming organisms. According to the United States, the Greek measure is an SPS measure, as it is applied to protect "plant life or health" from the "spread of pests"; to protect "human life or health" from "contaminants" or "disease-causing organisms in food"; or "to prevent or limit other damage" from the "spread of pests".

7.2818 **Canada** notes that the Greek safeguard measure was predicated on concerns that release into the environment of Topas oilseed rape may have a detrimental effect on the surrounding plant life or health. More specifically, Greece indicated that it was concerned about genetic escape from the biotech varieties, leading to the transfer of herbicide resistance through hybridization with wild oilseed rape varieties. In essence, the concerns of Greece were related to potential risks arising from the release into the environment of the biotech oilseed rape varieties because of their alleged potential to function as a "pest" in relation to the surrounding environment, and in particular, related wild species of oilseed rape.

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[1772] C/UK/95/M5/1.

[1773] Commission Decision 98/291 (Exhibits US-97; CDA-61).

[1774] Greece, Minister of Environment, Regional Planning and Public Works, Prohibition of seeds of the genetically-modified rape-plant line bearing reference number C/UK/95/M5/1, Government Gazette, 1008, 25 September 1998, at 11941 (Exhibits CDA-72; US-69).

7.2819 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2820 The **Panel** notes that the Ministerial decision adopted by the Greek authorities on 8 September 1998 prohibiting imports of Topas oilseed rape refers, without elaboration, to potential "risks for the natural environment of Greece".[1775] Greece provided the justification for its safeguard measure in a Note addressed to the Commission on 3 November 1998.[1776]

7.2821 In this document, Greece indicated that although the consent for Topas oilseed rape was not given for cultivation, the seeds could nonetheless escape into the environment during transport and grow into viable plants. Greece notes that since oilseed rape is capable of out-crossing and giving fertile hybrids with wild *Brassica* species, the release into the environment of oilseed rape could therefore generate hybrid plants bearing the glufosinate tolerance gene. The Greek climate would permit the spreading not only of volunteer oilseed rape plants, but also of their hybrids with wild related species in both the agricultural and the natural environment, with unpredictable consequences.[1777] Greece further notes that in Greece some of the wild plant varieties at issue are collected and consumed as food. Greece points out in this regard that if out-crossing were to confer on these wild plant varieties the herbicide resistance trait, the consequences of the consumption of these varieties would be unpredictable.

7.2822 Furthermore, in a letter form the Greek authorities to the Commission dated March 2004[1778] Greece highlights concerns about gene flow through pollen transfer to wild related species. This letter also notes that the maintenance of the safeguard measure at issue is justified by the precautionary principle, until new scientific information was available regarding risks to human health and the environment.

7.2823 Finally, we note that a memorandum was provided by Greece to the Commission in March 2004.[1779] It recalls the concerns underlying the safeguard measure on Topas oilseed rape, including those relating to the harm for wildlife and the environment and possible problems for consumers and farmers, specifically related to possible consumption of hybrids from outcrosses of Topas oilseed rape and wild plant species and the potential difficulties associated with managing herbicide tolerant weeds arising from these types of outcrosses. The memorandum concludes that the maintenance of the safeguard measure at issue is justified by the precautionary principle, pending complete scientific proof of the existence and seriousness of risks. The memorandum also states that the issue of co-existence is not relevant in the case of the oilseed rape since its import by Greece, if it were allowed, would be for the use of the product for oil extraction and not for cultivation.

7.2824 Based on the foregoing, we consider that at the time of review by the Panel, Greece applied its safeguard measure to address concerns about:

(1) adverse environmental effects of hybridisation and out-crossing;
(2) adverse environmental effects of volunteer Topas oilseed rape plants; and
(3) consumer health.

[1775] Exhibit EC-162/At. 4_trans.
[1776] *Ibid.*
[1777] *Ibid.*
[1778] Exhibit EC-162/At. 6.
[1779] Exhibit EC-162/At. 7.

7.2825 The European Communities asserts that Greece's safeguard measure on Topas oilseed rape is also applied in view of concerns about labelling and co-existence. These asserted concerns were not articulated by Greece in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Greece is applying its safeguard measure to address these additional concerns identified by the European Communities.

7.2826 Having determined the purposes for which Greece applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Greece's safeguard measure.

*Adverse environmental effects of hybridisation and out-crossing*

7.2827 We begin with Greece's stated purpose of managing risks associated with the environmental impacts of hybridisation and out-crossing. We recall that the documentation reviewed by the Panel with respect to the Greek safeguard measure on Topas oilseed rape highlighted concerns regarding the potential loss of seeds during transportation, which could result in the establishment of viable biotech oilseed rape in the environment and potential hybridisation with other *Brassicae*. The Panel understands this concern to be related, *inter alia*, to potential out-crossing between Topas oilseed rape plants and unmodified plants, and the introduction of herbicide resistance in the out-crossed plants.

7.2828 We refer to our finding in Section VII.C that cross-breeds between conventional and GM plants could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide resistance) and harm animal or plant life or health or result in other damage. We have determined on that basis that measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) from the entry, establishment or spread of cross-breeds with undesired traits resulting from the transfer of genetic material from a GM plant fall within the scope of Annex A(1)(a), while measures applied to prevent "other damage" to the environment from the entry, establishment or spread of cross-breeds fall within the scope of Annex A(1)(d).

7.2829 In addition, we recall that one possible concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or different, more toxic herbicides, to control the resistant cross-breeds. We determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We deduced from this that measures applied to avoid such indirect adverse effects on the environment fall within the scope of Annex A(1)(a) and (d).

7.2830 Consistent with our findings above, we consider that Greece's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid risks to the environment associated with the transfer of the herbicide-tolerance gene contained in Topas oilseed rape to wild related species, and in particular the development of resistance in these wild hybrid plants, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Adverse environmental effects of volunteer Topas oilseed rape plants*

7.2831 We next turn to Greece's concerns about other adverse environmental effects, notably adverse environmental effects of volunteer Topas oilseed rape plants which are the result of accidental dispersal of Topas oilseed rape seeds during transportation.

7.2832 In Section VII.C we found that to the extent a measure is applied to avoid adverse effects on plant life or health, including adverse effects on genetic diversity, that might arise if volunteer GM plants crowd out or eliminate other plants due to a potential competitive advantage, invasiveness or persistence, such a measure would be covered by Annex A(1)(a), as it would be applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

7.2833 In Section VII.C we also found that to the extent that volunteer GM plants may result in changes in plant populations, this may increase or decrease the food available for particular animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce. We stated that, by causing harm to the health of animals or other plants in this way, the GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a).

7.2834 Finally, we found that to the extent a measure seeks to avoid adverse effects of GM plants on the environment other than adverse effects on animal or plant life or health, such a measure can be considered to be covered by Annex A(1)(d), inasmuch as it can be viewed as a measure which is applied to prevent or limit "other damage" from the entry, establishment or spread of "pests". As noted earlier, the GM plants themselves might qualify as the relevant pest, or other plants or animals might become pests as a result of the release of GMOs into the environment.

7.2835 Consistent with our findings above, we consider that Greece's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid adverse effects on the environment arising from volunteer Topas oilseed rape plants, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Consumer health*

7.2836 Turning last to Greece's stated concern regarding the potential risks to consumer health associated with Topas oilseed rape, we recall that Greece expressed concern with respect to consumer health, since some wild varieties of oilseed rape are apparently consumed in Greece as food. Specifically, Greece noted that if out-crossing were to confer on these wild plant varieties the herbicide resistance trait, the consequences of the consumption of these varieties would be unpredictable. We understand this concern to be related to potential adverse health effects associated with the consumption of GM material or the consumption of proteins produced through the expression of modified genes, in hybrids of conventional oilseed rape and Topas oilseed rape.

7.2837 In Section VII.C we found that Annex A(1) covers food safety risks which might potentially arise from the consumption of GM foods, namely, risks to human life or health from the presence in food of additives, contaminants, toxins (including allergens) or disease-causing organisms. More particularly, we found that genes intentionally added for a technological purpose to GM plants that are eaten or being used as an input in processed foods can be considered "additives" in foods within the meaning of Annex A(1)(b). We also recall our finding that substances which are produced through

the unintended expression of modified plant genes may be considered "contaminants" within the meaning of Annex A(1)(b). Finally, we recall our finding that a poisonous substance which is produced during the metabolism or growth of a plant, including allergens, could qualify as a "toxin" within the meaning of Annex A(1)(b). Therefore, we consider that potential risks to human health associated with consumption of hybrids of GM and conventional cultivated or wild plants can be considered to be risks associated with "additives", "contaminants" or "toxins" in foods within the meaning of Annex A(1)(b). Measures applied to protect from such food safety risks can thus be considered to fall within the scope of Annex A(1)(b).

7.2838 Greece did not specify the nature of the potential adverse health effects associated with the consumption of cross-breeds between Topas oilseed rape and wild oilseed rape. Hence, we cannot determine whether Greece's concern relates to the presence in hybrids of additives, contaminants or toxins (including allergens). However, in the absence of any information suggesting otherwise, there are no grounds for believing that Greece's concern about consumer health does not relate to any of the aforementioned types of risks potentially associated with the consumption of GM foods.

7.2839 Thus, consistent with our findings above, we consider that Greece's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid risks to consumer health associated with the consumption of cross-breeds between Topas oilseed rape and wild oilseed rape, or food products derived therefrom, falls within the scope of Annex A(1)(b) of the *SPS Agreement*.

*Conclusion with regard to the purpose of the safeguard measure*

7.2840 In the light of the above considerations, we therefore conclude that the safeguard measure applied by Greece with respect to Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2841 We now turn to the issue of the form and nature of Greece's safeguard measure on Topas oilseed rape. We start by recalling the arguments of the Parties on this matter.

7.2842 The **United States** argues that the measure is in the form of a ministerial decision, which is synonymous with the term "regulation", which is one of the types of measure explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2843 **Canada** argues that the measure falls within the scope of "laws, decrees, regulations, requirements and procedures." As indicated by the use of the word "include", Annex A provides a non-exhaustive list of the forms that an SPS measure can take. The Greek measure is in the form of a "ministerial decision". Although this form of measure is not explicitly mentioned in Annex A, it can be equated to a regulation or other form of subordinate legislation, if legally binding and lawfully promulgated by the central government authorities.

7.2844 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing

of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2845 We note that Greece's safeguard measure on Topas oilseed rape was implemented through a ministerial decision to prohibit commercialization of Topas oilseed rape on the Greek territory. Annex A(1) does not specifically refer to "ministerial decisions". As we have pointed out, this fact alone does not necessarily mean that Greece's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Greece's decision clearly is a measure attributable to the Greek Government. It is also not in dispute that the decision is legally binding. We therefore consider that, for the purposes of Annex A(1), the Greek decision may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2846 In respect of the nature of the Greek measure, we note that the decision prohibits the marketing of Topas oilseed rape. As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2847 We therefore conclude that the safeguard measure taken by Greece with respect to Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2848 We have now considered Greece's safeguard measure on Topas oilseed rape in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Greece's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by Greece with respect to Topas oilseed rape constitutes an "SPS measure" within the meaning of Annex A(1).

7.2849 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Greek safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Canada or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Greek safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Greek safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2850 We now turn to the issue of whether Greece's safeguard measure on Topas oilseed rape is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Greece's safeguard measure on Topas oilseed rape to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2851 The **United States** argues that the measure adopted by Greece prohibits the "importation" of Topas oilseed rape. The measure as such therefore affects international trade.

7.2852 **Canada** argues that the measure prohibits the importation of Topas oilseed rape on the Greek territory. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2853 The **Panel** notes that the arguments of the parties regarding the effects on trade of Greece's safeguard measure on Topas oilseed rape are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize above. Therefore, in view of the fact that Greece's safeguard measure prohibits imports of Topas oilseed rape, we have no difficulty concluding that the safeguard measure applied by Greece is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2854 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Greek safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the Greek safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(ix) Italy – T25 maize, MON810 maize, MON809 maize, Bt-11 maize (EC-163)*

7.2855 We now turn to the Italian safeguard measure applied on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We recall that the applications for placing on the market of these products were originally submitted to the United Kingdom.[1780] The products were authorized by the European Commission under the simplified authorization procedure set out in Article 3(4) of Regulation 258/97.[1781] By Decree of the President of the Council of Ministers dated 4 August 2000 (hereafter "the Decree"), Italy adopted a measure pursuant to Article 12 of Regulation 258/97 to suspend the commercialisation and use on its territory of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163).[1782]

[1780] Exhibit EC-163.
[1781] Commission Decision 98/292 (Exhibits CDA-80; ARG-35).
[1782] Italy, President of the Council of Ministers, Precautionary suspension of the commercialisation and utilization of certain transgenic products [Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25

Is the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) an SPS measure?

7.2856 We start with the issue of whether the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is an SPS measure[1783]. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2857 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A (1) of the *SPS Agreement*.

7.2858 The **United States** notes that according to the SCF, one of the documents provided by Italy suggested that the herbicide tolerant biotech products Bt-11 maize and T25 maize could have adverse effects on consuming animals. The United States also notes that with respect to the products protected by Bt toxin (Bt-11, MON810 maize, MON809 maize), Italy cited another report which raised the issue of "occupational allerg[ies] to Bt bacterium spores in farmers using Bt pesticides". Based on these justifications, the Italian measure is an SPS measure, given that it is applied "to protect [...] animal life or health" from "contaminants, toxins or disease-causing organisms" in "feedstuffs"; or "to protect human life or health" from "toxins" in "foods".

7.2859 **Canada** notes that the Italian measure was predicated on concerns about the finding of substantial equivalence of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) to existing foodstuffs pursuant to Article 3(4) of Regulation 258/97. Canada argues that these concerns were triggered by laboratory tests which indicated that the products in question contained proteins derived from genetic modification at levels ranging from 0.04 to 30 parts per million.[1784]

7.2860 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2861 The **European Communities** argues that the main concerns with regard to T25 maize were, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health. With regard to MON810 maize, the concerns related to, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or

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maize] in the national territory, according to Article 12 of Regulation (European Communities) No. 258/97, 4 August 2000, Official Gazette, 8 August 2000, 184 (Exhibit EC-157/At. 1).

[1783] In respect of the safeguard measure imposed by Italy, while the complaints by the United States and Canada refer to four products, *i.e.*, Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize, the complaint by Argentina refers to only three products, *i.e.*, Bt-11 maize (EC-163), MON810 maize and T25 maize.

[1784] Exhibit CDA-86.

allergenicity; development of resistance; biodiversity; monitoring; labelling; co-existence; and human and animal health. Finally, with regard to MON809 maize and Bt-11, the European Communities asserts that the concerns of Italy relate to, *inter alia*, toxicity and allergenicity; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2862 The **Panel** notes that the Italian Decree sets out the reasons for Italy's decision to suspend the trade in and use of transgenic foodstuffs.[1785] In the Decree, Italy notes its concerns with respect to the simplified procedure under Regulation 258/97 pursuant to which the products at issue were authorized by the Commission. In particular, Italy points to the ambiguity of the term "substantial equivalence" in Article 3(4) of Regulation 258/97. In a letter addressed to the Commission before the adoption of the safeguard measure, the Italian authorities expressed their concern with the assessment carried out as part of the simplified procedure to evaluate whether a particular product is "substantially equivalent" to existing equivalent foods or food ingredients, in terms of its potential risks to human health or the environment.[1786] Similar concerns were also expressed in a subsequent letter addressed by the Italian Health Minister to the President of the European Commission and the Health and Consumer Protection Commissioner on 5 June 2000.[1787] The Decree further states that since it had been established that residues of modified components remain in the four products, the information available from the simplified procedure was also inadequate with regard to the risks arising from "environmental release" of the GMOs in question, or their products.

7.2863 The reasons set out in the Italian Decree are further based on opinions from the Italian *Consiglio Superiore di Sanità* (hereafter the "Superior Council of Health") and the *Istituto Superiore di Sanità* (hereafter the "Superior Institute of Health"). We note that the opinion of the Superior Council of Health of 16 December 1999 was not submitted to the Panel. However, according to the text of the Decree, the Superior Council of Health calls in its opinion for specific research to be undertaken on the consequences of genetic modifications before novel foodstuffs are placed on the market.[1788]

7.2864 The opinion of the Superior Institute of Health dated 28 July 2000, which is also mentioned in the Italian Decree, addresses the concept of "substantial equivalence" in the context of the product applications.[1789] In particular, the opinion identifies shortcomings in the original applications with respect to the data required to support the establishment of substantial equivalence of the product to its conventional counterpart.[1790] In this respect, the Superior Institute of Health notes that the maize products in question contain levels of protein deriving from the genetic modifications ranging from 0.04 to 30 parts per million and that, therefore, the foodstuff has been permanently affected by the modified elements. Italy observes in the Decree that even though the Superior Institute of Health concluded that there were no apparent risks to the health of humans or livestock from the consumption of derivatives of the biotech products, there were inadequacies in the risk assessment procedures.[1791]

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[1785] *See supra*, footnote 1782.

[1786] The Decree refers to a letter from the Italian Health Minister to the European Health and Consumer Protection Commissioner dated 23 December 1999, which is referenced internally as document No. 100/338.7/13126. On the basis of this reference number, the Panel notes that this letter is one of the translated documents submitted by the European Communities in Exhibit EC-157/At. 2_trans.

[1787] Exhibit EC-157/At. 2_trans.

[1788] *See supra*, footnote 1782.

[1789] We note that this opinion from the Superior Institute of Health is one of the translated documents provided by the European Communities in Exhibit EC-158/At. 2_trans.

[1790] *Ibid.*

[1791] *See supra*, footnote 1782.

7.2865 The opinion of the Superior Institute of Health also raises the issue that the herbicide glyphosate is metabolised by the herbicide-tolerant biotech plant to a non-toxic metabolite, but that this metabolite can revert to the parent compound in the gut of test animals. The opinion of the Superior Institute mentions in this context a recently published observation on occupational allergy to Bt bacterium spores in farmers using Bt pesticides.[1792] Furthermore, the Superior Institute of Health addresses in its opinion the issue of antibiotic resistance transfer, but concludes that "[t]he effect on antibiotic resistance of a possible resistant gene transfer from the GMOs to the components of the intestinal flora is minimal compared to the prevalence of antibiotic-resistant genes normally present in the intestinal flora of humans and animals."[1793] Finally, the Institute opinion also indicates that observations regarding the risk of possible "environmental release" of the GMOs in question, or of their products, are unnecessary.

7.2866 Based on the foregoing, we consider that at the time of review by the Panel, Italy applied its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) to address concerns about:

(1) adverse effects on consumer health due to the possibility that the herbicide glyphosate could revert from its non-toxic metabolite back to its original chemical composition in the gut of humans[1794]; and

(2) adverse effects on the environment arising from "environmental release" of the GM plants in question, or of the products derived therefrom.

7.2867 The European Communities asserts that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is also applied in view of concerns about labelling. However, this concern asserted by the European Communities was not articulated by Italy in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Italy is applying its safeguard measure to address the additional concern identified by the European Communities.

7.2868 Having determined the purposes for which Italy applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure.

*Consumer health*

7.2869 We consider first Italy's concerns regarding risks to human health arising from the consumption of food or food ingredients from the relevant GM plants, due to the possibility that the herbicide glyphosate could revert from its non-toxic metabolite back to its original chemical composition in the human gut.

7.2870 With respect to this concern, we recall our analysis in Section VII.C regarding contaminants, specifically our conclusion that the term "contaminants" in Annex A(1)(b) could encompass herbicide residues present in foods, and that these residues may have adverse effects on human life or health, such as allergenic effects. We determined on that basis that measures applied to protect human life or

[1792] *Ibid.*
[1793] *Ibid.*
[1794] This concern was raised generally in Exhibit EC-157/At. 1, and more specifically in Exhibit EC-157/At. 2.

health from risks arising from pesticide residues, and hence contaminants, in GM plants used as or in foods can be considered to fall within the scope of Annex A(1)(b).

7.2871 Consistent with our reasoning above, we consider that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), to the extent it is applied to avoid potential risks to human health arising from residues in food of the herbicide glyphosate, which is associated with the cultivation of the aforementioned biotech products and thus linked to these products, falls within the scope of Annex A(1)(b) of the *SPS Agreement*.

*Environmental release*

7.2872 We now consider the second concern identified by Italy, that the information available from the simplified procedure under which the relevant GMOs were approved was inadequate with regard to risks arising from "environmental release" of the GMOs in question or their products. Although no further explanation of this concern is provided in Italy's Decree, and although the Italian Superior Institute of Health indicated that any observations regarding the risk to the environment of possible "environmental release" were unnecessary, it appears to us that Italy was concerned about potential adverse effects on the environment which might arise from "environmental release" of the GMOs in question or their products.

7.2873 In Section VII.C we found that measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of (i) GM plants *qua* "pests", (ii) cross-breeds with undesired traits resulting from transfer of genetic material from a GM plant or (iii) other animals or plants which become pests as a result of the release of GMOs into the environment, are measures within the scope of Annex A(1)(a). We have also determined in Section VII.C that measures applied to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health, including on geochemical processes, can be considered as measures applied to prevent "other damage" to the environment resulting from the entry, establishment or spread of a pest and, as such, are covered by Annex A(1)(d).

7.2874 Consistent with our reasoning above, we consider that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), to the extent it is applied to address potential risks to the environment arising from the "environmental release" of these GMOs, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Conclusion with regard to the purpose of the safeguard measure*

7.2875 In the light of the above considerations, we conclude that the safeguard measure applied by Italy with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2876 We now turn to the issue of the form and nature of Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We start by recalling the arguments of the Parties on this matter.

7.2877 The **United States** argues that the Italian measure is in the form of a "decree", which is one of the types of measures expressly enumerated in Annex A(1) of the *SPS Agreement.*

7.2878 **Canada** argues that the Italian measure is in the form of a "decree", one of the types of measures expressly enumerated in Annex A(1) of the *SPS Agreement*.

7.2879 **Argentina** notes that the measure was taken in the form of a decree, one of the forms explicitly mentioned in Annex A(1).

7.2880 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2881 We note that Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) was implemented through a decree to prohibit commercialization of the products concerned on the Italian territory. We note that Annex A(1) specifically refers to "decrees". We therefore consider that, for the purposes of Annex A(1), the Italian decree is an SPS measure in respect of the form of the measure.

7.2882 In respect of the nature of the Italian measure, we note that the decree prohibits the marketing of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2883 We therefore conclude that the safeguard measure taken by Italy with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2884 We have now considered Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Italy's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by Italy with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) constitutes an "SPS measure" within the meaning of Annex A(1).

7.2885 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Italian safeguard measure could be considered to embody more than one SPS measure. However, neither the Complaining Parties nor the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Italian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Italian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2886 We now turn to the issue of whether Italy's safeguard measure with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2887 The **United States** argues that the measure adopted by Italy bans the "commercialization and use" of T25 maize, MON810 maize, MON809 maize and Bt-11 maize, thereby effectively blocking the importation of these products on the Italian territory. The measure as such therefore affects international trade, and meets the second requirement under Article 1.1 of the *SPS Agreement*.

7.2888 **Canada** notes that the measure suspends the commercialization of the maize biotech varieties T25 maize, MON810 maize, MON809 maize and Bt-11. Since the measure effectively blocks market access for the targeted biotech products, it clearly affects international trade.

7.2889 **Argentina** notes that since the safeguard measure prevents access of T25 maize, MON810 maize, MON809 maize and Bt-11 maize to Italy, resulting in the absence of imports of these products, the measure can be said to affect international trade.

7.2890 The **Panel** notes that the arguments of the parties regarding the effects on trade of Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) are the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609above. Therefore, in view of the fact that Italy's safeguard measure prohibits imports of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), we have no difficulty concluding that the safeguard measure applied by Italy is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2891 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize

(EC-163) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Italian safeguard measure on T25 maize, MON810 maize and Bt-11 maize (EC-163) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

*(x) Luxembourg – Bt-176 maize*

7.2892 We now turn to the safeguard measure applied by Luxembourg on Bt-176 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1795] The product was authorized by the European Commission in 1996[1796], and Luxembourg adopted its safeguard measure to prohibit the sale of Bt-176 maize on its territory pursuant to Article 16 of Directive 90/220 by a Ministerial Order issued in February 1997.[1797]

Is the Luxembourg safeguard measure on Bt-176 maize an SPS measure?

7.2893 We start with the issue of whether Luxembourg's safeguard measure on Bt-176 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2894 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2895 The **United States** notes that in the preamble of its decision to adopt a safeguard measure concerning Bt-176 maize, Luxembourg refers to potential risks for human health related to the antibiotic resistant gene. The United States argues that the safeguard measure is an SPS measure, as it is applied "to protect human life or health" from "toxins or disease-causing organisms in foods".

7.2896 **Argentina** argues that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

[1795] C/F/94/11-03.
[1796] Commission Decision 97/98 (Exhibits US-97, ARG-37).
[1797] Luxembourg, Journal Officiel du Grand Duché de Luxembourg, A – No.10, 28 February 1997, p. 618 (Exhibit US-63).

7.2897 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2898 The **Panel** notes that Luxembourg explained the reasons for its safeguard measure in a document submitted to the Commission at the time of notification of its measure (hereafter the "Reasons document").[1798] The document identifies two main concerns for the adoption of the safeguard measure, namely the transfer of the antibiotic (ampicillin)-resistance gene to the bacteria of the intestinal tract of animals, and the development of insect resistance to Bt toxin. With respect to the transfer of the ampicillin-resistance gene, Luxembourg justifies its measure by arguing that although the risk is low, some of the mechanisms operating in such a transfer are still being studied. With respect to the development of insect resistance to Bt toxin, Luxembourg notes that given the risks involved, the commercialization of Bt-176 maize should be made conditional upon the adoption of relevant monitoring programmes.

7.2899 Based on the foregoing, we consider that at the time of review by the Panel, Luxembourg applied its safeguard measure on Bt-176 maize to address concerns about:

(1) the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of animals; and

(2) the development of resistance to Bt toxin in insects.

7.2900 The European Communities asserts that Luxembourg's safeguard measure on Bt-176 maize is also applied in view of concerns about labelling, co-existence, out-crossing, and toxicity and allergenicity. The asserted concerns were not articulated by Luxembourg in the Reasons document discussed above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Luxembourg is applying its safeguard measure to address these additional concerns identified by the European Communities.

7.2901 Having determined the purposes for which Luxembourg applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Luxembourg's safeguard measure.

*Transfer of the bla-ampicillin resistance gene to bacteria of the intestine of animals*

7.2902 We consider first Luxembourg's stated concern regarding the potential transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of animals due to consumption of Bt-176 maize. The concern identified by Luxembourg with regard to Bt-176 maize is similar to that identified by Austria with regard to its safeguard measures T25 maize and Bt-176 maize. Thus, as in Austria's case, we refer to our discussion in Section VII.C regarding ARMG, and in particular our view that the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the

[1798] The document is entitled "Interdiction provisoire d'importer le maïs génétiquement modifié ayant subi la modification combinée lui assurant les propriétés insecticides conférées par le gène Bt-endotoxine et une meilleure résistance à l'herbicide glufosinate-ammonium – Motivation de la décision luxembourgeoise", communicated to the Commission with the "Arrêté ministériel" on 17 March 1997 (Exhibit EC-158/At. 9).

possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2903 In Section VII.C we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect animal life or health from risks arising indirectly, namely *via* the potential transfer to animals of marker genes conferring resistance to antibiotics used in veterinary medicine, from additives in feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2904 Consistent with our reasoning above, we consider that Luxembourg's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of animals, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

*Development of resistance to Bt toxin in insects*

7.2905 Turning now to Luxembourg's stated concern regarding potential risks associated with the development of resistance to Bt toxin in insects, we understand the concern identified by Luxembourg to be that resistance in insects to Bt toxin may develop due to frequent exposure to this pesticide (the Bt toxin) and that the development of high levels of resistance in insect populations might require the application of a pesticide where none was used before, the increased application of a pesticide, or the application of more harmful pesticides to control the resistant populations.

7.2906 We refer to our analysis in Section VII.C regarding the development of pesticide-resistance in insects. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determine that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We find that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2907 In view of the above findings, we consider that Luxembourg's safeguard measure on Bt-176 maize, to the extent it is applied to protect from potential risks associated with the development of resistance to Bt toxin in insects due to the cultivation of Bt-176 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

*Conclusion with regard to the purpose of the safeguard measure*

7.2908 In the light of the above considerations, we conclude that the safeguard measure applied by Luxembourg with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2909 We now turn to the issue of the form and nature of Luxembourg's safeguard measure on Bt-176 maize. We start by recalling the arguments of the Parties on this matter.

7.2910 The **United States** argues that the measure was enacted by ministerial "decree", a form of measure explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2911 **Argentina** notes that the measure was adopted in the form of an "arrêté ministériel", which is defined as a "written decision by an administrative authority". The term "décret" is defined as "a decision by the governmental authority by which the effects are similar to those of laws". According to Argentina, an "arrêté ministériel" is similar in nature to a decree, which is one of the measures listed in Annex A.

7.2912 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2913 We note that Luxembourg's safeguard measure on Bt-176 maize was implemented through an "arrêté ministériel", or a Ministerial Order, to prohibit the commercialization of Bt-176 maize on Luxembourg's territory. Annex A(1) does not specifically refer to "Ministerial Orders". As we have pointed out, this fact alone does not necessarily mean that Luxembourg's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Luxembourg's decision clearly is a measure attributable to Luxembourg's Government. It is also not in dispute that the decision is legally binding. We therefore consider that, for the purposes of Annex A(1), Luxembourg's decision may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2914 In respect of the nature of Luxembourg's measure, we note that the decision prohibits the marketing of Bt-176 maize. As indicated above, we are of the view that a prohibition of the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2915 We therefore conclude that the safeguard measure taken by Luxembourg with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2916 We have now considered Luxembourg's safeguard measure in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Luxembourg's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the overall conclusion that the safeguard measure taken by Luxembourg with respect to Bt-176 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2917 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, Luxembourg's safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat Luxembourg's safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat Luxembourg's safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2918 We now turn to the issue of whether Luxembourg's safeguard measure on Bt-176 maize is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Luxembourg's safeguard measure on Bt-176 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2919 The **United States** argues that the measure adopted by Luxembourg prohibits the "use and sale" of Bt-176 maize, thereby effectively blocking the importation of the product. The measure as such therefore affects international trade.

7.2920 **Argentina** notes that since the safeguard measure prevents access of Bt-176 maize to Luxembourg's territory, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2921 The **Panel** notes that the arguments of the parties regarding the effects on trade of Luxembourg's safeguard measure on Bt-176 maize are the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that Luxembourg's safeguard measure prohibits imports of Bt-176 maize, we have no difficulty concluding that the safeguard measure applied by Luxembourg is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2922 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that Luxembourg's safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

> With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that Luxembourg's safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(b) Preliminary issue: The relationship between Article 5.1 and Article 5.7 of the *SPS Agreement*

7.2923 We have determined above that the *SPS Agreement* is applicable to all safeguard measures which are being challenged. If we were to follow the Complaining Parties' approach, we would now proceed to examine the consistency of the relevant safeguard measures with Article 5.1 of the *SPS Agreement*, which requires that these safeguard measures be based on a risk assessment, as appropriate to the circumstances. The European Communities objects to this manner of proceeding, arguing that the safeguard measures at issue, to the extent they fall within the scope of the *SPS Agreement*, fall to be assessed under Article 5.7 of the *SPS Agreement*, to the exclusion of Article 5.1. Article 5.7 stipulates that in cases where relevant scientific evidence is insufficient, SPS measures may be provisionally adopted on the basis of available pertinent information.

7.2924 The European Communities presents two arguments in support of its contention that the safeguard measures must not be assessed under Article 5.1. *First*, the European Communities argues that the safeguard measures are provisional measures, and that, for this reason, the applicable provision is Article 5.7, and not Article 5.1. *Secondly*, the European Communities argues, more broadly, that the relationship between Article 5.1 and Article 5.7 is one of exclusion, and that Article 5.7 is not an exception to Article 5.1. We will address these arguments below and will then determine whether to assess the safeguard measures under Article 5.1, as requested by the Complaining Parties.

*(i) "Provisionally adopted" SPS measures*

7.2925 It is useful to begin our consideration of the EC argument concerning "provisionally adopted" SPS measures by setting out the text of relevant provisions.

7.2926 Article 2.2 provides:

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

7.2927 Article 5.1 provides:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

7.2928 Article 5.7 provides:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available

> pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

7.2929 In relation to Article 5.7, the Appellate Body has found that there are four requirements which a Member must meet in order to adopt and maintain a provisional SPS measure as contemplated in Article 5.7. These requirements are:[1799]

(a) the measure is imposed in respect of a situation where "relevant scientific evidence is insufficient";

(b) the measure is adopted "on the basis of available pertinent information";

(c) the Member which adopted the measure "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and

(d) the Member which adopted the measure "review[s] the … measure accordingly within a reasonable period of time".

7.2930 The **European Communities** argues that Article 5.7 contains specific rules regarding provisional measures, and that it is therefore by reference to these rules, not the rules in Article 5.1, that the safeguard measures must be assessed. Regarding Article 5.7, the European Communities submits that it applies only to provisional measures. In the European Communities' view, if, objectively, an SPS measure is "provisionally adopted", it falls within the scope of Article 5.7. The European Communities considers that the Appellate Body in *Japan – Apples* confirmed this when it stated that "[w]hen a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether 'relevant scientific evidence is insufficient'".[1800] In the European Communities' view, this statement indicates that the provisionality is the "demarcation line" between Article 5.1 and Article 5.7.

7.2931 The European Communities considers that Article 5.1 also supports its view. According to the European Communities, Article 5.1 concerns risk assessments to be carried out for SPS measures other than provisional SPS measures. The European Communities contends that for provisional SPS measures the first sentence of Article 5.7 requires an "assessment", but not a "risk assessment" as that term is defined in the *SPS Agreement*. The European Communities points out in this connection that the second sentence of Article 5.7 refers to a "more objective assessment", which in the European Communities' view means an assessment that is more objective than that to be carried out on the basis of the first sentence of Article 5.7. Thus, the European Communities maintains that the first sentence of Article 5.7 implies the need for an "assessment", but one which is different from the risk assessment envisaged in Article 5.1.

7.2932 The European Communities further submits that its view that provisional measures are not subject to Article 5.1 does not imply that provisional measures are not subject to a full set of controls under the *SPS Agreement*. Rather, in the European Communities' view, there are two "parallel universes" in the *SPS Agreement*, one for definitive measures and another for provisional measures. According to the European Communities, provisional measures must comply with the requirements of

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[1799] Appellate Body Reports, *Japan – Agricultural Products II*, para. 89; *Japan – Apples*, para. 176.
[1800] Appellate Body Report, *Japan – Apples*, para. 179.

Article 5.7, as well as with those of Articles 2.1[1801], 2.3[1802] and 2.4[1803] of the *SPS Agreement*. The European Communities considers that these provisions contain rules and obligations that are analogous to those set out in Articles 2.2 and 5.1 to 5.6 for definitive measures.

7.2933 Having regard to the present dispute, the European Communities asserts that all of the safeguard measures at issue are provisional measures within the meaning of Article 5.7. The European Communities notes in this regard that the text of the applicable EC legislation provides that member States may "provisionally restrict" (Article 16 of Directive 90/220) or "temporarily restrict" (Article 12 of Regulation 258/97) the use of a biotech product which has received EC-wide marketing approval. The European Communities further argues that the European Court of Justice has confirmed that measures adopted based on the aforementioned legislation are temporary measures.[1804] Finally, the European Communities submits that the provisional nature of the safeguard measures is also reflected in the text of these measures as well as the national laws on which these measures are based.

7.2934 The **United States** argues that in order to be covered by Article 5.7, a measure must meet each of the criteria set out in that paragraph. The mere label of a measure as "provisional" is not sufficient to bring it within the scope of Article 5.7. Regarding the safeguard measures at issue, the United States also notes that none of these measures satisfies the four criteria set out in Article 5.7. Specifically, the evidence is sufficient to perform a risk assessment, because the EC itself has conducted positive risk assessments for each product subject to a member State measure. Secondly, the EC's own scientific committees have confirmed that the member State measures are not based on "available pertinent information." Third, there is no information in the record that the Member States have sought to perform risk assessments that would support their bans. Fourth, the EC argument that "measures are constantly subject to review"[1805] does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

7.2935 **Canada** argues that neither in the text of the *SPS Agreement* nor in relevant jurisprudence is there a basis for the European Communities' bifurcation of the SPS regime on the basis of whether measures are "definitive" or "provisional". Neither in *Japan – Agricultural Products II* nor in *Japan – Apples* did the panels or the Appellate Body characterize provisionality as an *a priori* condition to be met for Article 5.7 to apply. In Canada's view, this strongly suggests that, for Article 5.7 to apply, it is not relevant whether the measure in question is expressed in provisional terms. What matters,

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[1801] Article 2.1 provides:

Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

[1802] Article 2.3 provides:

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

[1803] Article 2.4 provides:

Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

[1804] The European Communities refers to Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others*, judgement of 9 September 2003, para. 109.

[1805] EC replies to Panel questions, para. 324.

according to Canada, is whether there is evidence to demonstrate that each of the conditions set out in Article 5.7 has been fulfilled. Canada submits in this regard that the first condition, which concerns the sufficiency of relevant scientific evidence, is qualitatively different from the other conditions. Canada considers that the first condition represents a logical threshold – a textual bridge – between Article 2.2 and Article 5.7.

7.2936 Regarding the present dispute, Canada notes that it is true that the EC legislation indicates that safeguard measures are meant to be temporary. Canada submits, however, that when one considers the five safeguard measures challenged by Canada, the provisional quality of safeguard measures is not obvious, as none of the five measures in question has been in place less than 45 months, and some have been in place for more than five years.

7.2937 **Argentina** argues that Article 5.7 is not applicable to any measure which is labelled or deemed "provisional". Rather, Article 5.7 establishes a specific requirement that a Member must meet if it wishes provisionally to adopt an SPS measure: relevant scientific evidence must be insufficient. Argentina considers, therefore, that for a measure to be covered by Article 5.7, what matters is not whether that measure is designed to be provisional or definitive, but whether there is sufficient relevant scientific evidence. Only in such cases may a Member provisionally adopt an SPS measure on the basis of available pertinent information.

7.2938 The **European Communities** responds that the sufficiency or insufficiency of scientific evidence cannot be the "demarcation line" between Article 5.1 and Article 5.7 in view of the statement by the Appellate Body in *Japan – Agricultural Products II* that insufficiency of relevant scientific evidence is one of four requirements set out in Article 5.7 and that "[t]hese four requirements are clearly cumulative in nature and are equally important for the purposes of determining consistency with this provision".[1806] According to the European Communities, this statement confirms that none of the four requirements has a special role to play in the demarcation of the respective scopes of Articles 5.1 and 5.7, and that these requirements are relevant to the question of consistency with Article 5.7, not to the question of the "demarcation line" to be drawn between Articles 5.1 and 5.7.

7.2939 The **Panel** recalls the European Communities' argument that, for the purposes of the Panel's analysis of the safeguard measures, the relevant provision is Article 5.7 rather than Article 5.1. We first turn to examine this argument in the light of Article 5.7 itself. The first sentence of Article 5.7 provides in relevant part that "[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information". The first sentence follows a classic "if – then" logic: if a certain condition is met (*in casu*, insufficiency of relevant scientific evidence), a particular right is conferred (*in casu*, the right provisionally to adopt an SPS measure based on available pertinent information). Thus, it is clear that Article 5.7 is applicable whenever the relevant condition is met, that is to say, in every case where relevant scientific evidence is insufficient.[1807] The provisional adoption of an SPS measure is not a condition for the applicability of Article 5.7. Rather, the provisional adoption of an SPS measure is permitted by the first sentence of Article 5.7.

[1806] Appellate Body Report, *Japan – Agricultural Products II*, para. 89

[1807] When we refer to the "applicability of Article 5.7", we address the issue of whether or not the right conferred by the first sentence of Article 5.7 is, in principle, available to a Member. In a specific case, a Member must, of course, satisfy the various requirements set forth in Article 5.7 if it wishes to benefit from the right conferred by Article 5.7.

7.2940 If the provisional adoption of an SPS measure had been intended as a condition for the applicability of Article 5.7, the first sentence of Article 5.7 would, in our view, have opened with a different phrase, such as "In cases where a Member provisionally adopts an SPS measure […]". Also, we note that in *Japan – Apples* the Appellate Body stated that "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but by the insufficiency of scientific evidence".[1808] The Appellate Body made no mention of any additional "triggering factors".

7.2941 The European Communities draws our attention to the statement by the Appellate Body in *Japan – Apples* that "[w]hen a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether 'relevant scientific evidence is insufficient'".[1809] According to the European Communities, this statement indicates that the provisional nature of a measure is what determines whether a measure falls within the scope of Article 5.7. We do not agree. The European Communities' interpretation is at odds with the aforementioned statement by the Appellate Body in *Japan – Apples* that "the application of Article 5.7 is triggered [...] by the insufficiency of scientific evidence". Reading the two statements by the Appellate Body harmoniously, we think that the statement identified by the European Communities must be understood as referring to a situation where a measure is claimed to be a provisional measure within the meaning of Article 5.7. In fact, the Appellate Body in *Japan – Apples* pointed out that "Japan claimed, in the alternative, that its measure is a provisional measure consistent with Article 5.7".[1810] In any event, we note that the Appellate Body in *Japan – Apples* did not begin its Article 5.7 analysis by examining whether the measure at issue was provisional, as claimed by Japan.

7.2942 The European Communities identifies another statement by the Appellate Body which it considers supports its position. In *Japan – Agricultural Products II*, the Appellate Body stated that "[the] four requirements [contained in Article 5.7] are clearly cumulative in nature and are equally important for the purposes of determining consistency with this provision".[1811] The European Communities submits that this statement confirms that the requirement that relevant scientific evidence be insufficient cannot be accorded a special role in the demarcation of the respective scopes of Articles 5.1 and 5.7. Here again, we consider that the European Communities' argument is at odds with the subsequent statement by the Appellate Body in *Japan – Apples* that "the application of Article 5.7 is triggered [...] by the insufficiency of scientific evidence". Moreover, we note that in *Japan – Agricultural Products II* the Appellate Body was addressing the issue of *consistency* with Article 5.7, not *applicability* of Article 5.7. It is correct to say that for the specific purposes of determining *consistency* with Article 5.7, all four requirements are "equally important", for if any one of these requirements is not met, a Member is not acting consistently with the provisions of Article 5.7.[1812]

7.2943 The European Communities considers that its view regarding Article 5.7 is consistent with the provisions of Article 5.1. In the European Communities' view, Article 5.1 prescribes risk assessment only for SPS measures other than provisionally adopted SPS measures. Article 5.1 requires Members to "ensure that their [SPS] measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health". We note, however, that Article 5.1 does not qualify the term "SPS measures". Thus, the text of Article 5.1 provides no basis for the EC argument that Article 5.1 prescribes risk assessment only for SPS measures other than provisionally adopted SPS measures.

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[1808] Appellate Body Report, *Japan – Apples*, para. 184.
[1809] Appellate Body Report, *Japan – Apples*, para. 179.
[1810] *Ibid.*, para. 170.
[1811] Appellate Body Report, *Japan – Agricultural Products II*, para. 89
[1812] We also address this issue below at paras. 7.3216-7.3220.

7.2944 Notwithstanding the lack of textual basis in Article 5.1, the European Communities argues that provisionally adopted SPS measures should not be considered to be subject to Article 5.1 because the first sentence of Article 5.7 also requires Members to carry out an "assessment". According to the European Communities, the "assessment" required by the first sentence of Article 5.7 is different from a "risk assessment" as that term is defined in the *SPS Agreement*.[1813] Even assuming the European Communities' argument regarding the required "assessment" were correct[1814], it is apparent from the text of Article 5.7 that such an "assessment" would only be necessary for SPS measures which were provisionally adopted in respect of situations where "relevant scientific evidence [was] insufficient". Article 5.7 is not applicable to SPS measures which were provisionally adopted in respect of situations where relevant scientific evidence was *not* insufficient. Therefore, even accepting the EC argument, Article 5.7 would not assist the European Communities in establishing that Article 5.1 does not apply to any provisionally adopted SPS measures, as first it would need to be established that these measures were adopted in respect of situations where relevant scientific evidence was insufficient.

7.2945 In response to a question from the Panel, the European Communities stated that the provisions of Article 2.2 confirm that provisionality is the "demarcation line" between Articles 5.1 and 5.7. The European Communities points out that Article 2.2 refers to SPS measures which are "maintained" while Article 5.7 refers to SPS measures which have been "provisionally adopted". The European Communities concludes from this that definitive measures fall to be assessed under Articles 2.2 and 5.1 while provisional measures fall to be assessed under Article 5.7. In our view, the verb "maintain" in Article 2.2 does not support the conclusion that only definitive measures are subject to Article 2.2. It is not apparent to us why a provisional measure could not likewise be "maintained" within the meaning of Article 2.2. The fact that Article 5.7, which is part of the context of Article 2.2, refers to SPS measures which have been "provisionally adopted", and that Article 2.2 does not explicitly refer to such measures, does not imply that any measure which has been "provisionally adopted" is excluded, *a priori*, from the scope of application of Article 2.2. Indeed, by its terms, Article 2.2 is applicable to "any" SPS measures.

7.2946 The European Communities advances another argument based on Article 2.2. The European Communities argues that the sufficiency or insufficiency of scientific evidence cannot have been intended as a "demarcation line" between Articles 2.2 and 5.1, on the one hand, and Article 5.7, on the other hand, because the word "sufficient" has different meanings in the context of Article 2.2 and Article 5.7. We see no force in this argument. Our view that Article 5.7 is applicable in every case where relevant scientific evidence is insufficient is based on the clause "[i]n cases where relevant scientific evidence is insufficient" in Article 5.7. The Appellate Body in *Japan – Apples* has clarified the meaning of the word "insufficient" as it appears in Article 5.7.[1815]

7.2947 The European Communities also puts forward the argument that Articles 2.1, 2.3 and 2.4 of the *SPS Agreement* serve to demonstrate that there are two "parallel universes" in the *SPS Agreement*, one for definitive measures and another for provisional measures. While we have no difficulty accepting that the "basic rights and obligations" set out in these provisions are in principle applicable to provisional SPS measures, we see nothing in the text of these provisions which would suggest that they are applicable exclusively to provisional SPS measures. In our view, the provisions in question are applicable also to definitive SPS measures. We note in this regard that Article 2 is captioned "Basic Rights and Obligations". In the light of this, we do not think that these provisions serve to

[1813] To recall, the second sentence of Article 5.7 refers to "a *more objective* assessment of risk" (emphasis added).

[1814] We further address this issue below at para. 7.2992.

[1815] Appellate Body Report, *Japan – Apples*, para. 179.

demonstrate that the *SPS Agreement* sets out separate and special regimes – "parallel universes", in the European Communities' parlance – for provisional SPS measures and for definitive SPS measures.

7.2948 For all these reasons, we are unable to accept the European Communities' argument that since the safeguard measures at issue are provisionally adopted SPS measures, they fall to be assessed under Article 5.7, to the exclusion of Article 5.1. The safeguard measures may or may not have been provisionally adopted. If they were provisionally adopted, this fact alone would not exclude the applicability of Article 5.1.

*(ii) Article 5.7 of the SPS Agreement – right or exception from the "general obligation" under Article 5.1?*

7.2949 We now examine the second argument put forward by the European Communities in support of its view that the safeguard measures must not be assessed under Article 5.1. To recall, the second argument is that the relationship between Article 5.1 and Article 5.7 is one of exclusion, not exception. In developing its argument, the European Communities made reference to Articles 3.1 and 3.3 of the *SPS Agreement*. The text of these provisions is set out below.

7.2950 Article 3.1 provides:

> "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3."

7.2951 Article 3.3 provides:

> "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5."[1816]

7.2952 The **European Communities** argues that the relationship between Articles 3.1 and 3.3 of the *SPS Agreement* is one of exclusion, not exception.[1817] The European Communities notes that Article 2.2 contains wording substantially identical to that of Article 3.1. According to the European Communities, it necessarily follows that the relationship between Article 2.2 and Article 5.7 is also one of exclusion. In other words, Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7. The European Communities further notes that in *EC – Hormones* the Appellate Body stressed that Article 2.2 and Article 5.1 must be constantly read together.[1818] The European Communities deduces from this that the relationship between Article 5.1 and Article 5.7 must, equally, be one of exclusion. Thus, in the European Communities' view, Article 5.7 is an autonomous right, and not an exception to Articles 2.2 and 5.1.

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[1816] (*original footnote*) For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

[1817] The European Communities refers to Appellate Body Report, *EC – Hormones*, para. 104.

[1818] The European Communities refers to Appellate Body Report, *EC – Hormones*, para. 180.

7.2953 In support of its view that Article 5.7 is not an exception to Article 2.2, the European Communities further argues that the text of Article 5.7 is incorporated by reference into the text of Article 2.2. The European Communities considers that Article 5.7 is therefore part of Article 2, which is entitled "Basic Rights and Obligations". In the European Communities' view, Article 5.7 thus sets out basic rights and obligations of equivalent status to the basic rights and obligations set out in Article 2.

7.2954 The European Communities notes that none of the Complaining Parties has presented a claim of violation under Article 5.7. The European Communities submits that in view of this circumstance, and given the fact that, in its view, the safeguard measures are provisional measures falling within the scope of application of Article 5.7, it is irrelevant whether the safeguard measures meet the four requirements of Article 5.7. By bringing a claim of inconsistency with Article 5.1, the European Communities maintains, the Complaining Parties have simply invoked the wrong provision. The European Communities considers that there is therefore no basis for the Panel to conclude that the safeguard measures are inconsistent with Article 5.1.

7.2955 Moreover, the European Communities considers that if the Panel nonetheless were to determine that the safeguard measures did not meet one of the requirements of Article 5.7, *e.g.*, because there was sufficient scientific evidence, the Panel would need to conclude that the provisional measure in question is inconsistent with Article 5.7, and not that Article 2.2 or Article 5.1 becomes the relevant applicable provision. The European Communities contends that this has been confirmed by the Appellate Body in *Japan – Agricultural Products II* when it stated that "[w]henever one of [the] requirements [of Article 5.7] is not met, the measure at issue is inconsistent with Article 5.7".[1819]

7.2956 The **United States** argues that Article 5.7 does not provide a basis for a claim of an alleged breach of a WTO obligation, but acts as a defence to shield measures that would otherwise violate Articles 2.2 and 5.1. The United States submits that Article 5.7 provides an exception to Article 2.2 as well as Article 5.1, as these two articles "should constantly be read together".[1820] The United States points out that in *Japan – Agricultural Products II* and *Japan – Apples* the responding party invoked Article 5.7 to defend the challenged measure. The complaining party did not assert Article 5.7 as an independent claim of violation in either dispute, nor did the panels in these disputes suggest that the complaining party should have invoked Article 5.7.

7.2957 With regard to the issue of burden of proof, the United States is not arguing in this dispute that the responding party has the burden of proof to show that Article 5.7 applies to a particular SPS measure. The United States considers that in the present dispute it has established that the member State safeguard measures are inconsistent with Articles 2.2 and 5.1. In the United States' view, this necessarily means that Article 5.7 does not apply. Moreover, by showing that each of the products subject to a member State safeguard measure was subject to positive risk assessments by the European Communities' own scientists, the United States has met any burden of proof to show that scientific evidence was not "insufficient" and that Article 5.7 does not apply.

7.2958 **Canada** argues that equating the relationship between Articles 2.2 and 5.1, and Article 5.7, with the relationship between Articles 3.1 and 3.3 is inappropriate because the purposes, and therefore the relationships between these articles, respectively, are quite different. Articles 3.1 and 3.3 represent "separate but equal" tracks to follow in adopting an SPS measure. A Member can adopt a measure that is based on a relevant international standard, where such a standard exists. Alternatively, a Member can adopt a measure in accordance with the provisions of Article 3.3, where

[1819] Appellate Body Report, *Japan – Agricultural Products II*, para. 89 (emphasis omitted).
[1820] The United States refers to Appellate Body Report, *EC – Hormones*, para. 180.

it seeks a level of protection that is higher than the level of protection implied by the international standard. Article 3.3 is not merely a qualified exemption from the basic obligation in Article 3.1. It is the expression of the autonomous right of Members to establish their own appropriate levels of protection.

7.2959 Canada argues that in contrast, Articles 2.2 and 5.7 are not "separate but equal" tracks for Members to follow. Canada submits that Article 5.7 does not exist as an option that can be freely chosen by the Member concerned in place of Articles 2.2 and 5.1. Canada points out that unlike Article 3.3, Article 5.7 is a temporary solution. Ultimately, Article 5.7 must give way to the basic obligation in Article 2.2. Canada further argues that the application of Article 5.7 logically only arises where it has been determined that a measure is maintained without sufficient scientific evidence, which, unless justified under Article 5.7, would amount to a violation of Article 2.2. For these reasons, Canada considers that Article 5.7 operates as an exception to Articles 2.2 and 5.1. Therefore, Canada maintains, it is only if a challenged measure is found by a panel to be inconsistent with Article 2.2 and/or Article 5.1 that Article 5.7 comes into play, provided the importing Member invokes the provision as a source of justification for maintaining the challenged measure. Canada considers that it would be the Member invoking Article 5.7 that would have the initial burden of demonstrating a prima facie case.

7.2960 **Argentina** argues that Article 5.7 operates as a defence for measures which would otherwise be inconsistent with Articles 2.2 and 5.1. Argentina considers that when a Member meets the conditions set out in Article 5.7, it is entitled to adopt and maintain a measure under Article 5.7, and to depart from the general conditions set out in Article 2.2. In Argentina's view, a failure to meet the first condition of Article 5.7 – namely, that relevant scientific evidence must be insufficient – does not lead to an infringement of Article 5.7. Rather, it would prevent the relevant Member from departing from the general conditions set out in Article 2.2. According to Argentina, it is up to the responding party to invoke a defence under Article 5.7 and to meet the burden of establishing that defence.

7.2961 The **Panel** finds it appropriate to begin its examination of the relationship between Article 5.1 and Article 5.7 by examining the relationship between Article 2.2 and Article 5.7. It should be noted in this regard that Article 5.1 and Article 2.2 should "constantly be read together"[1821], and that Article 2.2 is an important part of the context of Article 5.1.

Relationship between Article 2.2 and Article 5.7

7.2962 The European Communities argues that Article 5.7 is not an exception to Article 2.2 in the sense that it could be invoked as an affirmative defence to a claim of violation under Article 2.2. Rather, the European Communities maintains, Article 5.7 establishes an autonomous right of the importing Member. The European Communities further submits that in cases where Article 5.7 is applicable, it is for the complaining party to establish that the importing Member has acted inconsistently with Article 5.7.

7.2963 In *EC – Tariff Preferences*, the Appellate Body was called on to determine whether the Enabling Clause constituted a right or an exception to Article I:1 of the GATT 1994. In that context, the Appellate Body made the following statement:

> "We recall that the Appellate Body has addressed the allocation of the burden of proof in similar situations. In cases where one provision permits, in certain circumstances, behaviour that would otherwise be inconsistent with an obligation in

[1821] Appellate Body Report, *EC – Hormones*, para. 180.

> another provision, and one of the two provisions refers to the other provision, the Appellate Body has found that the complaining party bears the burden of establishing that a challenged measure is inconsistent with the provision permitting particular behaviour *only* where one of the provisions suggests that the obligation is not applicable to the said measure. Otherwise, the permissive provision has been characterized as an exception, or defence, and the onus of invoking it and proving the consistency of the measure with its requirements has been placed on the responding party. However, this distinction may not always be evident or readily applicable."[1822]

7.2964 As an illustration of a case of two WTO provisions where the "permissive provision" was characterized by the Appellate Body as a right rather than an exception, the Appellate Body cited a paragraph in its report in *EC – Hormones*.[1823] The paragraph in question addresses the relationship between Article 3.1 and Article 3.3 of the *SPS Agreement*. The paragraph states in relevant part that:

> "Article 3.1 of the *SPS Agreement* simply excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement, that is, where a Member has projected for itself a higher level of sanitary protection than would be achieved by a measure based on an international standard. Article 3.3 recognizes the autonomous right of a Member to establish such higher level of protection, provided that that Member complies with certain requirements in promulgating SPS measures to achieve that level. The general rule in a dispute settlement proceeding requiring a complaining party to establish a *prima facie* case of inconsistency with a provision of the *SPS Agreement* before the burden of showing consistency with that provision is taken on by the defending party, is *not* avoided by simply describing that same provision as an 'exception'."[1824]

7.2965 Later in the same report, the Appellate Body found that:

> "[T]his right of a Member to establish its own level of sanitary protection under Article 3.3 of the *SPS Agreement* is an autonomous right and *not* an 'exception' from a 'general obligation' under Article 3.1."[1825]

7.2966 Returning to the general test enunciated by the Appellate Body in *EC – Tariff Preferences*, we note that, indeed, the relationship between Article 3.1 and Article 3.3 may be described as one where "one provision [namely, Article 3.3] permits, in certain circumstances, behaviour that would otherwise be inconsistent with an obligation in another provision [namely, the obligation in Article 3.1 to base SPS measures on international standards], [where] one of the two provisions [namely, Article 3.1] refers to the other provision, [and] where one of the provisions [namely, Article 3.1] suggests that the obligation [in Article 3.1 to base SPS measures on international standards] is not applicable" to measures falling within the scope of Article 3.3. With regard to this last element, we note that Article 3.1 contains the clause "except as otherwise provided for in this Agreement, and in particular in paragraph 3".

7.2967 The European Communities submits that we should conceive of the relationship between Article 2.2 and Article 5.7 in the same way that the Appellate Body conceived of the relationship between Article 3.1 and Article 3.3. The European Communities notes in this regard that there are

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[1822] Appellate Body Report, *EC – Tariff Preferences*, para. 88 (footnotes omitted).
[1823] *Ibid.*, footnote 189.
[1824] Appellate Body Report, *EC – Hormones*, para. 104.
[1825] *Ibid.*, para. 172.

significant textual similarities between Article 3.1 and Article 2.2. Indeed, whereas Article 3.1 contains the clause "except as otherwise provided for in this Agreement, and in particular in paragraph 3", Article 2.2 contains the closely similar clause "except as provided for in paragraph 7 of Article 5". It is clear from the Appellate Body's statement in *EC – Tariff Preferences* that in the context of Article 3.1, the relevant clause played an important part in the Appellate Body's determination of whether Article 3.3 constituted a right or an exception. As a result, we agree with the European Communities that we may in principle attach similar weight to the corresponding clause in Article 2.2, provided there is also a correspondence of the other elements highlighted by the Appellate Body in its statement in *EC – Tariff Preferences*.

7.2968 Evaluating the relationship between Article 2.2 and Article 5.7 in the light of the general test provided by the Appellate Body in *EC – Tariff Preferences*, we consider that the relationship in question is one where "one provision [namely, Article 5.7] permits, in certain circumstances, behaviour [namely, the provisional adoption of SPS measures in cases where scientific evidence is insufficient on the basis of available pertinent information] that would otherwise be inconsistent with an obligation in another provision [namely, the obligation in Article 2.2 not to maintain SPS measure without sufficient scientific evidence], [where] one of the two provisions [namely, Article 2.2] refers to the other provision, [and] where one of the provisions [namely, Article 2.2, and in particular the clause "except as provided for in paragraph 7 of Article 5"] suggests that the obligation [in Article 2.2 not to maintain SPS measure without sufficient scientific evidence] is not applicable" to measures falling within the scope of Article 5.7.

7.2969 Thus, we find the general test provided by the Appellate Body in *EC – Tariff Preferences* to be applicable, and application of that test leads us to the conclusion that Article 5.7 should be characterized as a right and not an exception from a general obligation under Article 2.2.[1826] In other words, we consider that in the same way that "Article 3.1 of the *SPS Agreement* [...] excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement"[1827], Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7. As we will explain further below, characterizing Article 5.7 as a right rather than as an exception has implications for the allocation of the burden of proof.

7.2970 We have said that Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7. We recall in this connection that Article 2.2 contains three distinct obligations. It is therefore important to note that the Appellate Body did not say that Article 5.7 operates as a qualified exemption from the first and second obligations in Article 2.2, *i.e.*, the obligation to ensure that SPS measures are applied only to the extent necessary to protect human, animal or plant life or health, and the obligation to ensure that they are based on scientific principles. In the present case, it is not necessary, however, to examine the legal issue of whether the phrase "except as provided for in paragraph 7 of Article 5" relates only to the third obligation contained in Article 2.2 – the obligation not to maintain SPS measures without sufficient scientific evidence – or whether it relates to all three obligations laid down in Article 2.2.

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[1826] Regarding our use of the term "right", we note that the Appellate Body's test in *EC – Tariff Preferences* does not provide a term to characterize the permissive provision in the kind of relationship we found to exist between Article 2.2 and Article 5.7. However, as we have noted, the Appellate Body referred to the relationship between Articles 3.1 and 3.3 as an illustration of the relevant kind of relationship. We have also pointed out that in *EC – Hormones*, the Appellate Body referred to the permissive provision, Article 3.3, as an "autonomous right", noting also that Article 3.3 does not constitute an exception from a general obligation under Article 3.1.

[1827] Appellate Body Report, *EC – Hormones*, para. 104.

7.2971 We note that Article 5.7 makes clear that SPS measures adopted and maintained pursuant to Article 5.7 are meant to be temporary in nature.[1828] In our view, the fact that Article 2.2 only temporarily excludes from its scope of application the kinds of situations covered by Article 5.7 does not detract from our characterization of Article 5.7 as a right. Where a right is conferred, it does not cease to be a right merely because it has been conferred on a temporary basis. Moreover, there is nothing unusual about the temporary inapplicability of a WTO provision. One need look no further than Article 14 of the *SPS Agreement*, which provides for specific transitional periods for least developed country Members and other developing country Members. During the applicable transitional periods, these Members are entitled to the non-application of some or all other provisions of the *SPS Agreement.*

7.2972 The view that Article 5.7 is not an exception in the nature of an affirmative defence is also consistent with the statement by the Appellate Body in *Japan – Agricultural Products II* that "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence".[1829] Had the Appellate Body been of the view that Article 5.7 operates as an exception under which an importing Member could justify an inconsistency with an applicable obligation, it would, in our view, have been more natural and appropriate to use the term "exception" rather than the term "exemption", as the term "exemption" connotes freedom from, and hence inapplicability of, an obligation.[1830]

7.2973 We stress that Article 5.7 does not establish an absolute or unqualified right. In *Japan – Agricultural Products II*, the Appellate Body made clear that there are four cumulative requirements in Article 5.7 which must be met in order for a Member to adopt and maintain a provisional SPS measure consistently with Article 5.7.[1831] We think that these requirements are the reason why the Appellate Body emphasised that "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence".[1832]

7.2974 In concrete terms, characterizing Article 5.7 as a qualified right rather than an exception means that if a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the situation is "as provided for in paragraph 7 of Article 5" (Article 2.2), and the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence is not applicable to the challenged measure. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the situation is not "as provided for in paragraph 7 of Article 5" (Article 2.2), and the relevant obligation in Article 2.2 is applicable to the challenged measure, provided there are no other elements which render Article 2.2 inapplicable.

7.2975 The European Communities draws our attention to the statement by the Appellate Body in *Japan – Agricultural Products II* that "[w]henever one of [the] requirements [of Article 5.7] is not

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[1828] The first sentence of Article 5.7 refers to SPS measures being "provisionally adopted" on the basis of available pertinent information, and the Appellate Body has noted that the requirements set out in the second sentence of Article 5.7 highlight the provisional nature of measures adopted pursuant to Article 5.7. Appellate Body Report, *Japan – Apples*, footnote 318.

[1829] Appellate Body Report, *Japan – Agricultural Products II*, para. 80 (emphasis in original).

[1830] The adjective "exempt" means "free from an obligation or liability imposed on others". *The Concise Oxford Dictionary*, 10th ed, J. Pearsall (ed.) (Clarendon Press, 1999), p. 498.

[1831] Appellate Body Report, *Japan – Agricultural Products II*, para. 89. *See also* Appellate Body Report, *Japan – Apples*, para. 176. We identify the four cumulative requirements contained in Article 5.7 above at para. 2.

[1832] Appellate Body Report, *Japan – Agricultural Products II*, para. 80 (emphasis in original).

met, the measure at issue is inconsistent with Article 5.7".[1833] The European Communities argues that in view of this statement, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the Panel should find that the challenged measure violates Article 5.7, and not that the relevant obligation in Article 2.2 is applicable to the measure in question. We do not consider that the aforementioned statement by the Appellate Body supports the European Communities' argument. To say, as the Appellate Body did, that a measure is "inconsistent" with Article 5.7 when the relevant requirements are not satisfied is not tantamount to saying that Article 2.2 is inapplicable to that measure. Indeed, as we have pointed out, the Appellate Body in *Japan – Agricultural Products II* also stated that Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. Moreover, the ordinary meaning of the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 indicates that Article 2.2 would be applicable in a situation where a measure meets some, but not all, of the requirements of Article 5.7.

7.2976 Characterizing Article 5.7 as a qualified right and not an exception also has implications for the allocation of the burden of proof concerning the issue of the consistency of an SPS measure with Article 5.7. According to the Appellate Body's statement in *EC – Tariff Preferences*, in cases where the permissive provision constitutes a right rather than an exception, "the complaining party bears the burden of establishing that a challenged measure is inconsistent with the provision permitting particular behaviour".[1834] And in *EC – Sardines*, the Appellate Body observed that "[i]n *EC – Hormones*, we found that a 'general rule-exception' relationship between Articles 3.1 and 3.3 of the *SPS Agreement* does not exist, with the consequence that the complainant had to establish a case of inconsistency with *both* Articles 3.1 and 3.3".[1835] We deduce from these two statements that in cases where a complaining party alleges that an SPS measure is inconsistent with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged SPS measure is inconsistent with at least one of the four requirements set forth in Article 5.7. If such non-compliance is demonstrated, then, and only then, does the relevant obligation in Article 2.2 apply to the challenged SPS measure.

7.2977 Our view of the nature of the relationship between Article 2.2 and Article 5.7 and of the proper allocation of the burden of proof under these provisions is consistent with that of the panel in *Japan – Agricultural Products II*. In that case, the United States as the complaining party claimed that the challenged measure was inconsistent, *inter alia*, with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence. After reaching the provisional conclusion that the challenged measure was inconsistent with Article 2.2, the panel noted that Japan, the responding party, was invoking Article 5.7 in support of its measure. Recalling the text of Article 2.2, and notably the clause "except as provided for in paragraph 7 of Article 5", the panel then stated that in view of Japan's invocation of Article 5.7 it needed to examine whether the challenged measure was a measure meeting the requirements in Article 5.7. The panel noted that "[i]f the [challenged measure] meets these requirements, we cannot find that it violates Article 2.2".[1836] The panel then went on to analyse the measure in the light of the requirements of Article 5.7, finding that "the United States [as the complaining party] has established a presumption that Japan did not comply with the requirements in the second sentence of Article 5.7. We also consider that Japan has not been

[1833] Appellate Body Report, *Japan – Agricultural Products II*, para. 89 (emphasis omitted).
[1834] Appellate Body Report, *EC – Tariff Preferences*, para. 88.
[1835] Appellate Body Report, *EC – Sardines*, para. 275 (emphasis in original).
[1836] Panel Report, *Japan – Agricultural Products II*, para. 8.48.

able to rebut this presumption".[1837] In the light of this finding, the panel then reached the overall and final conclusion that the challenged measure was inconsistent with Article 2.2.[1838]

7.2978 We note that in a later case, *Japan – Apples*, the panel confronted a very similar situation. In that case, the United States as the complaining party also claimed that the challenged measure was inconsistent with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence. Japan as the responding party contested this claim, but argued, in the alternative, that its measure was consistent with the requirements of Article 5.7. The panel recalled the approach followed by the panel in *Japan – Agricultural Products II*, stating that it agreed with that approach and that it would therefore make no final findings with respect to the consistency of the measure at issue with Article 2.2 until it had completed its analysis under Article 5.7.[1839] However, contrary to the approach of the panel in *Japan – Agricultural Products II*, the panel in *Japan – Apples* determined that "the burden [was] on Japan, as the party invoking Article 5.7, to make a prima facie case in support of its position".[1840] The panel did not elaborate further on why it had decided to place this burden of proof on Japan. Following the approach it had outlined, the panel then determined, on a provisional basis, that the challenged measure was inconsistent with Article 2.2. The panel next examined Japan's alternative argument under Article 5.7, finding that Japan had failed to establish that its measure was justified under Article 5.7. In view of this finding, the panel confirmed its provisional conclusion under Article 2.2, finding that the challenged measure was inconsistent with Article 2.2.[1841]

7.2979 In relation to the approach followed by the panel in *Japan – Apples*, it is important to point out that the Appellate Body in that same case noted that "[t]he Panel's assignment of the burden of proof to Japan to make a *prima facie* case of consistency with Article 5.7 is not challenged on appeal".[1842] We take this statement as a reservation expressed by the Appellate Body in respect of the panel's assignment of the burden of proof to Japan. In any event, as we have stated above, and for the reasons stated above, we consider that it is incumbent on the complaining party to establish a prima facie case of inconsistency with both Articles 2.2 and 5.7.

7.2980 Before proceeding to analyse the relationship between Article 5.1 and Article 5.7, we wish to address two arguments presented by Canada. First of all, Canada invokes basic logic in support of its position that Article 5.7 should be considered as an exception. In Canada's view, it is logically necessary to determine first whether a measure is maintained without sufficient evidence within the meaning of Article 2.2. Canada submits that only if a measure is maintained without sufficient evidence, the question arises whether maintaining that measure is nonetheless justifiable under Article 5.7. Canada's argument is based on the premise that Article 2.2 is applicable in the kinds of situations covered by Article 5.7. However, such a premise does not comport well with the text of Article 2.2. Indeed, the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 suggests the opposite of what Canada is assuming, namely, that the relevant obligation in Article 2.2 is *not* applicable in situations covered by Article 5.7. If, as we believe, Article 2.2 was not intended to apply in the situations covered by Article 5.7, it made entire sense for the drafters to include the aforementioned exclusionary clause in the text of Article 2.2. Conversely, if, as Canada argues, Article 5.7 was intended to constitute an affirmative defence to a claim of violation under Article 2.2, it was unnecessary to include the aforementioned exclusionary clause in the text of Article 2.2. The

[1837] *Ibid.*, para. 8.58.
[1838] *Ibid.*, para. 8.61.
[1839] Panel Report, *Japan – Apples*, para. 8.201.
[1840] *Ibid.*, para. 8.212.
[1841] *Ibid.*, paras. 8.199, 8.222 and 8.224.
[1842] Appellate Body Report, *Japan – Apples*, footnote 316.

"logical" way of giving expression to such an intention would have been for Article 2.2 not to include the aforementioned exclusionary clause, and for Article 5.7 to state that "notwithstanding the provisions of Article 2.2, in cases where relevant scientific evidence is insufficient, Members may provisionally adopt SPS measures on the basis of available pertinent information".[1843] Thus, while our view accounts for, and gives meaning and effect to, all of the terms used in Article 2.2, Canada's view renders the exclusionary clause effectively redundant. We recall in this regard that in interpreting Article 2.2, we must give meaning and effect to all of its terms – "*ut res magis valeat quam pereat*" – and must not adopt an interpretation which would result in rendering some of its terms effectively redundant.[1844]

7.2981 In any event, the logic argued for by Canada could also be said to apply to the relationship between Article 3.1 and Article 3.3. Thus, by the same token, it could be said that it is only once it has been determined that an SPS measure is not based on an existing international standard that it becomes relevant to ask whether a Member may nevertheless depart from that standard to achieve a higher level of protection. Yet the Appellate Body found that Article 3.3 is not an exception to a "general obligation" in Article 3.1.

7.2982 The second argument put forward by Canada which we wish to comment on is Canada's argument that, for the purposes of interpreting the relationship between Articles 2.2 and 5.7, any reliance on the Appellate Body's interpretation in *EC – Hormones* of the relationship between Article 3.1 and Article 3.3 would be misplaced and inappropriate. According to Canada, Article 3.1 and Article 3.3 give Members the free choice of basing their SPS measures either on an international standard or on a stricter national standard. In contrast, Canada maintains, Members do not have the option of either maintaining SPS measures with sufficient scientific evidence, as contemplated in Article 2.2, or of maintaining SPS measures on the basis of available pertinent information, as contemplated in Article 5.7. As an initial matter, we note that Articles 3.1 and 3.3 are part of the context of Articles 2.2 and 5.7. Moreover, we consider that there is an undeniable structural and textual similarity between Articles 3.1 and 3.3 and Articles 2.2 and 5.7. Both pairs of articles are linked to each other through a textual cross-reference, and Article 3.1 contains an "except as provided for" clause which is textually almost identical to the corresponding clause in Article 2.2. It is primarily this structural and textual similarity of Articles 3.1 and 3.3, coupled with the fact that these provisions, and their mutual relationship, have already been interpreted by the Appellate Body, which renders them relevant to, and hence has factored in, our examination of the relationship between Article 2.2 and Article 5.7.

7.2983 Thus, our view of the relationship between Articles 2.2 and 5.7 is not reliant on the premise that the relationship between Articles 3.1 and 3.3, on the one hand, and Articles 2.2 and 5.7, on the other hand, is the same in all respects. Indeed, we agree with Canada that there are important substantive differences. A Member can, subject to compliance with applicable requirements, choose whether to base an SPS measure on a relevant international standard in line with Article 3.1 or, alternatively, to avail itself of the qualified right not to do so provided in Article 3.3. In contrast, in cases where the relevant scientific evidence is insufficient, *e.g.*, because none is available, a Member who wishes nonetheless to take a precautionary SPS measure could not meet the requirement in Article 2.2 to ensure that this measure "is not maintained without sufficient scientific evidence". This further strengthens our conviction that Article 5.7 should be viewed as a qualified exemption from the relevant obligation in Article 2.2, confirming the right of Members to take measures which are "necessary for the protection of human, animal or plant life or health" in situations where the available scientific evidence is "insufficient". Therefore, while recognizing the existence of substantive

[1843] *See*, for a similar argument, Appellate Body Report, *US – Upland Cotton*, para. 609.
[1844] *See also* Appellate Body Report, *US – Gasoline*, p. 23.

differences between Articles 3.1 and 3.3, on the one hand, and Articles 2.2 and 5.7, on the other hand, we do not consider that these differences support Canada's view that Article 5.7 constitutes an exception to Article 2.2 in the nature of an affirmative defence.

Relationship between Article 5.1 and Article 5.7

7.2984 We now turn to examine the relationship between Article 5.1 and Article 5.7. We recall at the outset that Article 5.1 requires Members to base their SPS measures on a risk assessment, whereas pursuant to Article 5.7, in cases where relevant scientific evidence is insufficient, Members may provisionally adopt SPS measures on the basis of available pertinent information. The European Communities submits that we should view the relationship between Article 5.1 and Article 5.7 in the same way that we view the relationship between Article 2.2 and Article 5.7. Or as the European Communities also put it, Article 5.7 is not an exception from a general obligation under Article 5.1, but an autonomous right.

7.2985 We recall that in accordance with the guidance provided by the Appellate Body in *EC – Tariff Preferences*, we could characterize Article 5.7 as a right in relation to Article 5.1 if the relationship between Article 5.1 and Article 5.7 is one "where one provision permits, in certain circumstances, behaviour that would otherwise be inconsistent with an obligation in another provision, [where] one of the two provisions refers to the other provision, [and] where one of the provisions suggests that the obligation is not applicable to the said measure".[1845] We will therefore examine below whether the relationship between Article 5.1 and Article 5.7 meets these various elements of the general test articulated by the Appellate Body.

7.2986 We consider first whether Article 5.7 permits, in certain circumstances, what would otherwise be inconsistent with Article 5.1. We note in this regard the statement by the panel in *Australia – Salmon* that "Article 5.7 allows for an exception to the obligation to base sanitary measures on a risk assessment, namely 'in cases where relevant scientific evidence is insufficient'".[1846] This statement clearly suggests that Article 5.7 permits what Article 5.1 prohibits. This statement also suggests that Article 5.7 constitutes an exception, although it is less than clear that the panel conceived of Article 5.7 as an exception in the nature of an affirmative defence. As the panel did not explain why it described Article 5.7 as an exception, we are bound to recall the above-quoted statement by the Appellate Body in *EC – Hormones* that characterizing a treaty provision as an "exception" does not, by itself, place the burden of proof on the responding party.[1847]

7.2987 Looking at the first sentence of Article 5.7, we note that, by its terms, it does not require that Members provisionally adopting SPS measures perform a risk assessment as defined in Annex A(4) to the *SPS Agreement*, and that they base their measure on the completed risk assessment as contemplated in Article 5.1. The first sentence of Article 5.7 requires that in cases where relevant scientific evidence is insufficient, SPS measures be adopted "on the basis of available pertinent information".

7.2988 We note that the second sentence of Article 5.7 obligates Members maintaining SPS measures under Article 5.7 to seek to obtain the additional information necessary for "a more objective assessment of risk", and to review their measures "accordingly". We understand the phrase "a more objective assessment of risk", taken as a whole, to refer to a risk assessment which satisfies the definition provided in Annex A(4) – or at least which is closer to satisfying the definition in

[1845] Appellate Body Report, *EC – Tariff Preferences*, para. 88.
[1846] Panel Report, *Australia – Salmon*, para. 8.57.
[1847] Appellate Body Report, *EC – Hormones*, para. 104.

Annex A(4) than consideration of "available pertinent information". This also appears to be the Appellate Body's view, for it stated in *Japan – Agricultural Products II* that:

> "Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct 'a more objective assessment of risk'. Therefore, the information sought must be germane to conducting *such a risk assessment*, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied."[1848]

7.2989 It is clear from this statement that by "such a risk assessment" the Appellate Body meant "a more objective assessment of risk". We consider that the use of "more" objective invokes a movement in a certain direction, that is, towards the eventual "objective" assessment of risk as defined in Annex A(4), *i.e.*, an evaluation of the likelihood of entry, establishment or spread of a pest, according to the SPS measures which might be applied.

7.2990 According to the Appellate Body, "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*".[1849] Thus, if a Member may provisionally adopt an SPS measure on the basis of available pertinent information in situations where the scientific evidence is insufficient for an adequate risk assessment, as required by Article 5.1 and as defined in Annex A(4), it makes sense to require, as the second sentence of Article 5.7 does, that that Member seek to obtain "the additional information necessary" for such a risk assessment. Once a Member has obtained the additional information necessary for a risk assessment which meets the definition of Annex A(4), it will be in a position to comply with its obligation in Article 5.1 to base its SPS measure on a risk assessment which satisfies the definition of Annex A(4).

7.2991 Based on the foregoing considerations, we think the second sentence of Article 5.7 does not support the view that SPS measures which have been provisionally adopted pursuant to Article 5.7 can be maintained only if they are based on a risk assessment as required under Article 5.1 and as defined in Annex A(4). However, there is one element of the second sentence of Article 5.7 which we need to examine further.

7.2992 The second sentence of Article 5.7 refers to "a *more objective* assessment of risk" (emphasis added). The element "more objective" suggests that SPS measures provisionally adopted pursuant to the first sentence of Article 5.7 must also be based on a risk assessment, namely, a risk assessment which takes into account available pertinent information. It follows that if the first sentence of Article 5.7 required a risk assessment, it would necessarily be different in nature from the kind of risk assessment envisaged in Annex A(4). In other words, any risk assessment which might be required by the first sentence of Article 5.7 would not need to meet the definition of a risk assessment contained in Annex A(4). The above-mentioned interpretation by the Appellate Body of the phrase "[i]n cases where relevant scientific evidence is insufficient" also supports this view. For if the right conferred by the first sentence of Article 5.7 only arises in cases where the scientific evidence is insufficient for an adequate risk assessment as required by Article 5.1 and as defined in Annex A(4), then the kind of risk assessment which the first sentence might require by definition could not meet the standard set out in Annex A(4).

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[1848] Appellate Body Report, *Japan – Agricultural Products II*, para. 92 (emphasis added).
[1849] Appellate Body Report, *Japan – Apples*, para. 179.

7.2993 In the light of the above, we consider that subject to compliance with the requirements set out in Article 5.7, SPS measures may be provisionally adopted and maintained under Article 5.7 even if these measures are not based on a risk assessment as defined in Annex A(4). Accordingly, we conclude that Article 5.7 permits Members to do, in certain circumstances, what they would not be permitted to do under Article 5.1.

7.2994 The next issue for consideration is whether either Article 5.1 or Article 5.7 refers to the other provision. The first thing to be noted with regard to this issue is that neither Article 5.1 nor Article 5.7 contains an explicit cross-reference to the other provision. Our previous discussion of the relationship between Article 5.1 and Article 5.7 shows, however, that Article 5.7 contains implicit references to Article 5.1. *First*, the second sentence of Article 5.7 refers to "a more objective risk assessment", a phrase which we have construed to refer to a risk assessment within the meaning given to that term in Annex A(4). We have also noted that only Article 5.1 requires a risk assessment as defined in Annex A(4). *Secondly*, we have noted earlier that according to the Appellate Body, relevant scientific evidence is "insufficient" within the meaning of the first sentence of Article 5.7 if it does not allow the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A(4). Thus, through its interpretation of the phrase "[i]n cases where relevant scientific evidence is insufficient", the Appellate Body has made explicit a reference to Article 5.1 which in its view is implicit in Article 5.7. Indeed, the Appellate Body justified its interpretation on the basis that there is "a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1".[1850] In view of these elements, we conclude that Article 5.7 should be considered to refer to Article 5.1.

7.2995 The last element we need to address in accordance with the general test set out in *EC – Tariff Preferences* is whether either Article 5.1 or Article 5.7 suggests that the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to measures falling within the scope of Article 5.7. We begin by noting that unlike Article 2.2, Article 5.1 does not explicitly say that its provisions apply "except as provided for in paragraph 7 of Article 5". However, Article 5.7 opens with the phrase "[i]n cases where relevant scientific evidence is insufficient". As mentioned by us before, the Appellate Body opined that "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*".[1851] Accordingly, if the right conferred by the first sentence of Article 5.7 only arises in cases where the scientific evidence is insufficient for an adequate risk assessment as defined in Annex A(4), and if, as the Appellate Body suggests, Article 5.1 requires such a risk assessment, then the logical conclusion to be drawn is that the obligation in Article 5.1 to base SPS measures on a risk assessment was not intended to be applicable to measures falling within the scope of Article 5.7. Indeed, "[i]n cases where relevant scientific evidence is insufficient", it is impossible, under the Appellate Body's interpretation of that phrase, for Members to meet the obligation to base their SPS measures on a risk assessment as defined in Annex A(4). We find it unreasonable to assume that Members would accept, even in principle, an obligation with which they cannot comply. In our view, the phrase "[i]n cases where relevant scientific evidence is insufficient" should, therefore, be taken to suggest that the obligation in Article 5.1 is not applicable to measures falling within the scope of Article 5.7.

7.2996 In addition, we think the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 also suggests that the obligation in Article 5.1 is not applicable to measures falling within the scope of Article 5.7. We recall in this regard that in *EC – Hormones* the Appellate Body agreed

[1850] *Ibid.*
[1851] *Ibid.*

with a statement by the panel in that case that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2.[1852] If Article 5.1 is properly viewed as a specific application of the obligations provided for in Article 2.2, it follows that Article 5.1 cannot be applicable in situations where Article 2.2 is not applicable. We have explained above that the clause "except as provided for in paragraph 7 of Article 5" exempts the kinds of situations covered by Article 5.7 from the obligation in Article 2.2 to ensure that SPS measures are not maintained without sufficient scientific evidence. Since Article 5.1 is not applicable in situations where Article 2.2 is not applicable, the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 necessarily implies that Article 5.1 cannot be applicable in situations covered by Article 5.7.

7.2997 From our analysis above, it is clear that the general test stated by the Appellate Body in *EC – Tariff Preferences* can be applied also to the relationship between Article 5.1 and Article 5.7. Our application of that test has shown that this relationship meets all the elements which according to the Appellate Body support characterizing Article 5.7 as a right *vis-à-vis* Article 5.1. Furthermore, we think it would be incongruous to reach the conclusion that Article 5.7 is a right *vis-à-vis* Article 2.2, but an exception *vis-à-vis* Article 5.1. For these reasons, we conclude that Article 5.7 should be characterized as a right also in relation to Article 5.1, rather than as an exception from a "general obligation" under Article 5.1. In our view, Article 5.7 operates as a qualified exemption from the obligation under Article 5.1 to base SPS measures on a risk assessment.

7.2998 We have already stated the main implications of characterizing Article 5.7 as a qualified right rather than as an exception in our discussion of the relationship between Article 2.2 and Article 5.7. Nonetheless, for clarity, it is useful to do so again given that we are concerned here with the relationship between Article 5.1 and Article 5.7. Thus, in terms of applicability of Article 5.1, characterizing Article 5.7 as a right means that if a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to the challenged measure. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the aforementioned obligation in Article 5.1 is applicable to that measure, provided there are no other elements which render Article 5.1 inapplicable.

7.2999 We note in this context that in relation to the safeguard measures at issue in this dispute, the European Communities has advanced the argument that in the event the Panel deemed Article 5.1 applicable, the phrase "as appropriate to the circumstances" in Article 5.1 would send the Panel right back to Article 5.7, because, in the European Communities' view, the safeguard measures in question are provisional measures, and the circumstances are that the scientific evidence is insufficient. The European Communities has not explained how the phrase "as appropriate to the circumstances" would "send the Panel back" to Article 5.7. We note that the European Communities' argument is premised on the applicability of Article 5.1. In view of the assumptions posited by the European Communities – provisional adoption of the safeguard measures in a situation where relevant scientific evidence is insufficient – Article 5.1 would be applicable only if the safeguard measures are not maintained consistently with the second sentence of Article 5.7. We fail to see how in such a case, that is, in a

[1852] Appellate Body Report, *EC – Hormones*, para. 180. *See also* Appellate Body Report, *Japan – Agricultural Products II*, para. 82. It appears that the Appellate Body views Article 5.1 as a specific application of the second and third obligation in Article 2.2, *i.e.*, the obligation to base SPS measures on scientific principles and the obligation not to maintain SPS measures without sufficient scientific evidence. In *Australia – Salmon*, the Appellate Body agreed with the panel in that case that in the event an SPS measure is not based on a risk assessment as required in Article 5.1, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence within the meaning of Article 2.2. Appellate Body Report, *Australia – Salmon*, para. 138.

case where the right conferred by Article 5.7 could not be validly asserted, the phrase "as appropriate to the circumstances" in Article 5.1 could "send the Panel back" to Article 5.7.

7.3000 We now turn to the implications of characterizing Article 5.7 as a qualified right rather than as an exception for the allocation of the burden of proof concerning the issue of the consistency of an SPS measure with Article 5.7. In our view, the implication is that in cases where a complaining party alleges that an SPS measure is inconsistent with Article 5.1, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged measure is inconsistent with at least one of the four requirements set forth in Article 5.7. If such non-compliance is demonstrated, then, and only then, is Article 5.1 applicable to the challenged SPS measure. Accordingly, we think that when a complaining party presents a claim of violation under Article 5.1, the burden is on the complaining party to establish a prima facie case of inconsistency with both Articles 5.1 and 5.7.

7.3001 We recognize that previous panels have found inconsistencies with Article 5.1 without specifically examining whether the complaining party had established a prima facie case of inconsistency with both Articles 5.1 and 5.7.[1853] In our view, this reflects the fact that in these cases the responding party did not invoke the provisions of Article 5.7 in response to a claim of violation under Article 5.1. In other words, in previous cases, the responding parties did not contest that the relevant measure fell to be assessed under Article 5.1 as opposed to Article 5.7. Since we are confronted in this case with a different situation, it would be improper for us to place the burden of establishing a prima facie case of inconsistency with Article 5.7 on the responding party on the grounds that panels in the past did not explicitly require of the complaining party that it establish a prima facie case of inconsistency with both Articles 5.1 and 5.7. The fact that responding parties in the past did not contest the applicability of Article 5.1 does not, and should not, preclude the responding party in the present case from doing so and thus asserting the right conferred on it by Article 5.7.

7.3002 Additionally, we note that if we had determined that Article 5.7 is an exception from a "general obligation" under Article 5.1, the burden would be on the responding party to demonstrate that the challenged measure is consistent with all of the requirements set forth in Article 5.7. In contrast, in the context of a claim under Article 2.2, it is, according to our view, incumbent on the complaining party to establish a prima facie case of inconsistency with Article 5.7. If we were to accept such a situation, a complaining party could unilaterally determine whether to assume the burden of establishing a prima facie case of inconsistency with Article 5.7. If it wished to avoid that burden, all it would need to do is to present a claim of violation under Article 5.1 rather than under Article 2.2. This, we think, is a further reason for conceiving of the relationship between Article 5.1 and Article 5.7 in the same way as of the relationship between Article 2.2 and Article 5.7.

*(iii) Conclusion*

7.3003 We have now completed our analysis of the two arguments presented by the European Communities in support of its contention that the safeguard measures must not be assessed under Article 5.1. Regarding the first argument, we have found that even if the European Communities were correct in asserting that the safeguard measures at issue in this dispute are provisional measures, this fact alone would not render Article 5.1 inapplicable.

7.3004 Regarding the second argument, we have determined that Article 5.7 does not provide for an exception from Article 5.1, but establishes a qualified right. We have said that, on this view of the

[1853] *But see*, Panel Report, *Australia – Salmon*, para. 8.57, where the panel intimated, in the context of an inquiry under Article 5.1, that the challenged measure was not consistent with Article 5.7.

relationship between Article 5.1 and Article 5.7, if an SPS measure challenged under Article 5.1 was adopted and is maintained consistently with the cumulative requirements of Article 5.7, the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to the challenged measure. In such a case, the complaining party would not have invoked the "wrong" provision, in the sense that it should have brought a challenge under Article 5.7 instead of Article 5.1. The complaining party would have invoked the "correct" provision, but the complaining party's claim under Article 5.1 could not succeed as long as the responding party complies with the requirements of Article 5.7.

7.3005 In the present case, the Complaining Parties are challenging the safeguard measures under Article 5.1. It is clear from the previous paragraph that, in such circumstances, it is both necessary and appropriate to examine the consistency of the safeguard measures with Article 5.7 within the context, and as part, of an examination of the consistency of the same measures with Article 5.1. Therefore, unlike the European Communities, we consider that we may, and indeed must, assess the safeguard measures under Article 5.1.[1854] Accordingly, in the next section, we will address the issue of the consistency of the individual safeguard measures with Article 5.1.

7.3006 Concerning the structure of our Article 5.1 analysis, one possibility would be to examine first whether the Complaining Parties have met their burden of establishing a prima facie case of inconsistency with Article 5.7 in respect of the relevant safeguard measures. However, in the specific circumstances of this case, the critical legal issue in our view is whether the relevant safeguard measures meet the requirements set out in the text of Article 5.1, not whether they are consistent with Article 5.7. Therefore, consistent with the order of analysis followed by the panels in *Japan – Agricultural Products II* and *Japan – Apples* when examining the consistency of measures with Articles 2.2 and 5.7, we prefer to begin our Article 5.1 analysis by examining whether the relevant safeguard measures meet the requirements set out in the text of Article 5.1, notably the requirement to base SPS measures on a risk assessment.

7.3007 Under this approach, should we find that a relevant safeguard measure meets the requirements set out in the text of Article 5.1, there would be no need to examine the Complaining Parties' claims under Article 5.1 further, as their claims would then fail even if we were satisfied that the safeguard measure is not consistent with Article 5.7 and that Article 5.1 therefore applies to the safeguard measure. Should we find, however, that the safeguard measure does not meet the requirements set out in the text of Article 5.1, we would need to go on to examine whether this measure is consistent with the requirements of Article 5.7. If the safeguard measure were consistent with the requirements of Article 5.7, Article 5.1 would not be applicable and we would consequently need to conclude that the European Communities has not acted inconsistently with its obligations under Article 5.1. Conversely, if the safeguard measure were inconsistent with the requirements of Article 5.7, Article 5.1 would be applicable and, in view of the assumed fact that the safeguard measure does not meet the requirements set out in the text of Article 5.1, we would need to conclude that the European Communities has acted inconsistently with its obligations under Article 5.1.

(c) Consistency with Article 5.1 of the *SPS Agreement* (initial assessment)

7.3008 As indicated, in this section, we will make an initial assessment of the consistency of the relevant safeguard measures with Article 5.1 of the *SPS Agreement*. Specifically, we will examine whether the safeguard measures meet the requirements set out in the text of Article 5.1. We begin this task by addressing a number of general arguments put forward by the Parties.

[1854] For clarity, we should mention that our assessment of the safeguard measures under Article 5.1 might lead us to conclude that Article 5.1 is not applicable.

*(i) General*

7.3009 To recall, Article 5.1 of the *SPS Agreement* provides:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

7.3010 Annex A(4) of the *SPS Agreement* provides the following definition of the term "risk assessment":

> "*Risk assessment* – The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

7.3011 We have already determined that the relevant safeguard measures are "SPS measures". As such, they are subject to the provisions of Article 5.1. Thus, the safeguard measures must be based on an appropriate risk assessment.

7.3012 The **United States** claims that the safeguard measures are not based on a risk assessment and are, therefore, inconsistent with Article 5.1. Although the member States have offered reasons for their measures, they did not put forth a risk assessment as defined in Annex A(4) of the *SPS Agreement*. The member States have expressed concerns about the potential adverse effects of the relevant products, or biotech products in general, but there is no evidence that these objections were based on any risk assessments. The only risk assessments put forth for the banned products are those conducted by the member States to which the product applications were originally submitted, and by the European Communities' own scientific committees. These risk assessments were favourable to the products, and did not raise any concerns with respect to human health or the environment. Given that the information provided by the member States in support of their measures was rejected by the EC scientific committees, which reaffirmed their initial favourable risk assessment, it cannot be argued that the safeguard measures bear a "rational relationship" to these risk assessments. The United States contends that by failing to put forth their own risk assessments, or to provide sufficient information to overturn the European Communities' earlier positive assessments, the member States have violated Article 5.1.

7.3013 **Canada** similarly argues that the safeguard measures are not based on a risk assessment, and therefore violate Article 5.1. Although the member States have presented reasons when notifying their safeguard measures to the Commission, they did not file any supporting scientific evidence or analysis that meets the definition of a risk assessment set out in the *SPS Agreement*. Canada notes that while the notifications to the Commission pointed to the shortcomings in the risk assessments done as part of the approval process, or put forward general concerns with respect to risks to human health or the environment arising from the banned varieties of biotech products, they did not present a comprehensive analysis of the available scientific evidence. Furthermore, the risk assessments undertaken by the member States where the products were originally filed and by the EC scientific committees both supported the approval of the product applications. The EC scientific committees also rejected in each case the reasons presented by the member States to justify the safeguard measures. Therefore, it cannot be argued that the risk assessments available sufficiently support or

reasonably warrant the safeguard measures, nor that there is a rational relationship between these risk assessments and the member States measures.

7.3014 **Argentina** also argues that the member States measures are inconsistent with Article 5.1 and Annex A(4) of the *SPS Agreement*. It notes that the member States have failed to perform a risk assessment within the meaning of the *SPS Agreement*. The safeguard measures, it argues, have been adopted and maintained without reference to any type of scientific evidence, and in spite of the scientific committee opinions which "disqualified" the member State measures as lacking any scientific basis.

7.3015 The **European Communities** argues that Article 5.1 does not expressly require a "risk assessment". It requires only that Members take into account risk assessment techniques developed by the relevant international organizations.[1855] According to the European Communities, these risk assessment techniques generally recognize that in certain circumstances, namely in the case of the adoption of provisional measures, only an assessment, and not a "risk assessment" within the meaning of the *SPS Agreement*, is necessary. The European Communities argues, in the alternative, that the member States' safeguard measures are based on risk assessments within the meaning of the *SPS Agreement*, as can be inferred from the history of each safeguard measure as well as the sequence of events which led the member States to adopt and maintain those measures.[1856] In its response to a question from the Panel, the European Communities notes that "[a] risk assessment was carried out at the time when the original […] consent was given" for the product, and that such risk assessment "can serve, at least temporarily, as a basis both for the original Community consent, and for the Member States provisional [safeguard] measures".[1857]

7.3016 The European Communities further contends that the requirement that an SPS measure be "based on" a risk assessment does not necessarily mean that this measure must "conform to" the risk assessment. The same risk assessment may "sufficiently warrant", or "reasonably support", more than one possible SPS measure, depending, *inter alia*, on the specific circumstances of the legislator. There may be both a mainstream scientific opinion on which responsible and representative governments may base themselves, and divergent scientific views on the basis of which equally responsible and representative governments may act. In other words, the same risk assessment can reasonably support divergent responses by equally responsible and representative governments. The European Communities also notes that in any event, the member States have made their own risk assessments, and that further risk assessments may be forthcoming.[1858]

7.3017 **Canada** disagrees with the EC argument that Article 5.1 does not expressly require a "risk assessment", but only that Members take into account risk assessment techniques developed by relevant international organizations. That Article 5.1 creates a clear obligation on Members to base their measures on a risk assessment is supported by the definition of the term "risk assessment" in Annex A(4), as well as relevant jurisprudence.[1859] Canada further notes that it fails to see how the risk assessments that formed the basis for the European Communities' approval of the products can serve as the basis for both the original Community consent and for the member States' safeguard measures.

[1855] EC reply to Panel question No. 107.
[1856] EC first written submission, para. 610.
[1857] EC reply to Panel question No. 107.
[1858] *Ibid.*
[1859] Canada argues that relevant jurisprudence supports the interpretation that Article 5.1 creates a clear obligation on the Members to base their measures on a risk assessment, and that it, together with Article 2.2, is "essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement* between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings" (Appellate Body Report, *EC – Hormones*, para. 177).

The publicly available scientific opinions do not equivocate in their conclusions, nor do they present diverging views on the potential risks associated with these products.

7.3018 Canada notes that while the Appellate Body has recognized in *EC – Hormones* that a risk assessment can reflect diverging views, and that responsible and representative governments may act in good faith on the basis of divergent opinions, it did not say that "the same risk assessment can reasonably support divergent responses by equally responsible and representative governments" in cases where the risk assessments do not contain divergent views. This must be all the more true when the contrast between the two risk management options, i.e. full approval or complete ban of the product, is as stark as in this case. Finally, with regard to the European Communities' suggestion that the member States have conducted their own risk assessment and that such assessments may be forthcoming, Canada notes that the European Communities has failed to present any evidence of such assessments having been undertaken.

7.3019 The **Panel** recalls that pursuant to Article 5.1, Members must "base" their SPS measures on a "risk assessment". To determine whether an SPS measure is consistent with Article 5.1, we must therefore address two distinct issues: (i) whether there is a "risk assessment" within the meaning of the *SPS Agreement*; and (ii) whether the measure is "based on" this risk assessment.

7.3020 In relation to the first issue, i.e., the issue of whether a risk assessment was carried out, we note the European Communities' argument that Article 5.1 does not expressly require a "risk assessment" within the meaning of the *SPS Agreement*, but only requires that Members take into account risk assessment techniques developed by relevant international organizations.

7.3021 To the extent the European Communities is arguing that there is no requirement to assess "risks", we disagree. By its own terms, Article 5.1 requires Members to base their SPS measures on an appropriate assessment "of the risks to human, animal or plant life or health".[1860] The immediate context of Article 5.1 confirms this view. Article 5 is captioned "*Assessment of Risk* and Determination of the Appropriate Level of Sanitary and Phytosanitary Protection" (emphasis added). Moreover, Articles 5.2 and 5.3 of the *SPS Agreement* specify relevant factors to be taken into account by Members "in the assessment of risks" and "in assessing the risk to animal or plant life or health". Finally, Article 5.7 of the *SPS Agreement* provides that in circumstances where relevant scientific evidence is insufficient and a Member has adopted a provisional SPS measure based on available pertinent information, it must seek to obtain the additional information necessary for a more objective assessment of "risk".

7.3022 As the European Communities points out, Article 5.1 provides that Members must base their SPS measures on an appropriate assessment of risks, "taking into account risk assessment techniques developed by relevant international organizations". In our view, the phrase "taking into account risk assessment techniques developed by relevant international organizations" does not address the issue of whether risks are to be assessed, but rather how risks are to be assessed. This is clear from the reference to "techniques" of risk assessment. Contrary to the European Communities, we therefore do not consider that the phrase in question supports the view that no assessment of risks is required. To the contrary, the phrase in question would, in our view, be unnecessary if there were no requirement to assess risks.

7.3023 The European Communities asserts that risk assessment techniques developed by the relevant international organizations generally recognize that in circumstances where provisional SPS measures

[1860] In *Japan – Apples*, the Appellate Body referred to an "obligation to conduct an assessment of 'risk'". Appellate Body Report, *Japan – Apples*, para. 202.

are adopted, an assessment is required, but not a "risk assessment" as that term is defined in the *SPS Agreement*. It is not clear to us what the European Communities means by "an assessment". If it means to say that some type of assessment of risks would be required, but not an assessment which meets the definition of the term "risk assessment" provided in Annex A(4), we see no basis for such an argument. It is well established in WTO jurisprudence that the Annex A(4) definition is applicable to Article 5.1.[1861] Moreover, since the definition of the term "risk assessment" in Annex A(4) does not itself provide for a particular risk assessment "technique", we have difficulty seeing how a particular risk assessment "technique" developed by an international organization could render inapplicable the general definition of the term "risk assessment" in Annex A(4). In any event, the European Communities has not identified the risk assessment techniques which it says support its assertion that a "risk assessment" within the meaning of Annex A(4) is not required in the case of provisional SPS measures. We therefore do not examine this argument further.

7.3024 We have said that, in our view, an assessment of risks is required. We recall in this respect that Article 5.1 of the *SPS Agreement* does not require a Member to conduct its own risk assessment. As noted by the Appellate Body in *EC - Hormones*, "Article 5.1 does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment. It only requires that the SPS measure be 'based on an assessment, as appropriate to the circumstances [...]'. The SPS measure might well find its objective justification in a risk assessment carried out by another Member, or an international organization".[1862] Thus, an SPS measure may be based on a risk assessment conducted by another Member, or an international organization.

7.3025 In the present case, the relevant member State safeguard measures might therefore be supported by a risk assessment carried out by these member States in respect of the product subject to their safeguard measures, or by a risk assessment performed by another entity.

7.3026 Regarding the possibility of there being a risk assessment performed by an entity other than the member State adopting a particular safeguard measure, we note that assessments were carried out in respect of the relevant products before their approval. Before their approval, assessments were performed by the CA of the member State to which the product application was originally submitted – the "lead CA"[1863]- and by the relevant EC scientific committee. Furthermore, after the approval of the product, these assessments were reviewed by the relevant EC scientific committee on the basis of the information provided by the member State adopting the safeguard measure.

7.3027 It is common ground among the Parties that the assessments carried out by the lead CA and by the EC scientific committees constitute "risk assessments" within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. It is apparent from the assessments provided to us that they evaluated the likelihood of potential adverse effects on human health and/or the environment, as well as the associated potential consequences, according to the proposed use of the specific biotech product under consideration.[1864] These assessments were of a qualitative and not quantitative nature, however the WTO jurisprudence has clearly established that the *SPS Agreement* does not require that risk assessments be of a quantitative nature in order to satisfy the definition in Annex A(4). We therefore

[1861] *See, e.g.*, Appellate Body Reports, *Japan – Apples*, para. 196; *Australia – Salmon*, para. 121.

[1862] Appellate Body Report, *EC - Hormones*, para. 190.

[1863] We note that for none of the nine safeguard measures at issue the member State adopting the safeguard measure acted as the lead member State during the relevant approval procedure.

[1864] We note that the assessments by the relevant EC scientific committees which reviewed these committees' earlier assessments in the light of information provided by the member States taking safeguard measures are generally in the nature of supplemental assessments. Thus, the review assessments need to be read in conjunction with the earlier (original) assessments.

agree with the Parties that risk assessments within the meaning of Annex A(4) and Article 5.1 have been conducted in respect of the products subject to the safeguard measures by the lead CA and by the relevant EC scientific committee. Below, we will examine for each safeguard measure whether, in addition, other risk assessments have been conducted in respect of these same products, and in particular whether the EC member States applying safeguard measures have carried out their own risk assessment.

7.3028 Once we have determined that one or more risk assessments exist in respect of a product subject to one of the relevant safeguard measures – and we have already found in the previous paragraph that such risk assessments exist – we must go on to analyse any claims that the relevant safeguard measure is "based on" one or more of these risk assessments. With respect to the issue of whether an SPS measure is "based on" a risk assessment, we note that this requirement has been interpreted as meaning that there must be a rational relationship between a risk assessment and the SPS measure taken, or in other words, that the results of the risk assessment must "sufficiently warrant" or "reasonably support" the SPS measure at issue.[1865]

7.3029 Consistent with the foregoing considerations, we will determine below, for each safeguard measure, whether there exists a "risk assessment" upon which the safeguard measure is "based". Before undertaking this task, however, we must address one further issue. The issue to be addressed is whether the maintenance of the relevant safeguard measures may be justified both by reference to risk assessments which were carried out before these measures were adopted and by reference to risk assessments which were carried out after these measures were adopted.

7.3030 Article 5.1 does not explicitly speak to this specific issue. We recall that Article 5.1 requires Members to ensure that their SPS measures "are based on" an assessment, "as appropriate to the circumstances", of risks to animal, plant or human life or health. Regarding the requirement that SPS measures be "based on" a risk assessment, it is clear to us that SPS measures must be "based on", or "sufficiently warranted" or "reasonably supported" by, a risk assessment throughout the period of time for which these measures are maintained.[1866] In our view, both a risk assessment carried out before the adoption of a particular safeguard measure and a risk assessment carried out after its adoption could "sufficiently warrant", or "reasonably support", the maintenance of that measure.

7.3031 Also relevant to our inquiry is the requirement that a risk assessment be "appropriate to the circumstances". The phrase "as appropriate to the circumstances" is unqualified as far as its temporal scope is concerned. Notably, Article 5.1 does not say "as appropriate to the circumstances existing at the time of adoption of such measures", or "as appropriate to the circumstances existing at the time of the assessment". We think it may be inferred from the absence of any temporal limitation that at any given time, SPS measures must be based on an assessment of risks which is appropriate to the circumstances existing at that time. Indeed, this is consistent with the fact that relevant circumstances may change over time.[1867] A change in relevant circumstances may have an impact on a completed

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[1865] Appellate Body Report, *EC - Hormones*, paras. 193-194.

[1866] This view is consistent with the following finding by the panel in *Australia – Salmon*:

> We note Australia's statement that its policy of allowing imports of salmon products heat-treated in accordance with the 1988 Conditions will be reviewed and that for these purposes an import risk analysis is scheduled. It is possible that this risk analysis provides a rational basis for the measure at issue. However, *as of today* and on the basis of the risk assessment before us, we do not detect such a basis. (Panel Report, *Australia – Salmon*, para. 8.100 (emphasis added).)

[1867] Article 2.2 also contains separate requirements supporting this view, stating that Members shall ensure that their measures are 1) "based on scientific principles" and 2) "not maintained without sufficient scientific evidence".

risk assessment, and in some cases the impact may be such as to affect the continued relevance of a completed risk assessment and the validity of its conclusions.[1868] If and when a change in relevant circumstances affects the continued relevance and validity of a completed risk assessment, that assessment would, in our view, no longer constitute an assessment "appropriate to the circumstances".[1869]

7.3032 We note that the Appellate Body observed that the phrase "as appropriate to the circumstances" provides Members with "a certain degree of flexibility in meeting the requirements of Article 5.1".[1870] However, this statement did not relate to a situation such as the one we are considering here where relevant circumstances change over time. We see nothing in the ordinary meaning of the phrase "as appropriate to the circumstances", or in the aforementioned observation by the Appellate Body, to contradict our view that a change in relevant circumstances could in some cases render a completed risk assessment no longer "appropriate to the circumstances".

7.3033 This approach is also supported by the context of Article 5.1. Article 5.6 provides that "when establishing or *maintaining* [SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" (emphasis added). We have previously observed that one of the purposes of a risk assessment is to allow the importing Member to determine the measure to be applied, if any, for achieving its appropriate level of protection. Thus, if a Member could maintain under Article 5.1 a significantly trade-restrictive SPS measure on the basis of a risk assessment which is no longer appropriate to the circumstances (*e.g.*, due to new scientific evidence which affects the continued relevance and validity of the risk assessment in question), and a risk assessment appropriate to the circumstances would establish that essentially no risk in fact exists, then that Member would be "maintaining" an SPS measure which *ex hypothesi* is more trade-restrictive than required to achieve its appropriate level of protection, contrary to the requirements of Article 5.6. Irrespective of whether the trade-restrictive measure could be challenged under Article 5.6, we consider that it would be improper to interpret Article 5.1 so as to allow the Member to maintain its trade-restrictive measure, as such an interpretation would frustrate an important purpose of a risk assessment, which is "to serve as a basis for regulatory actions"[1871]. The determination of a measure which is not more trade-restrictive than required to achieve a Member's appropriate level of protection is a relevant "regulatory action".

7.3034 In the present case, the Complaining Parties are challenging the maintenance by the European Communities of the relevant safeguard measures. Thus, in accordance with our interpretation of Article 5.1 we must examine whether, on the date of establishment of this Panel, each safeguard measure was based on an assessment of risks which was appropriate to the circumstances existing at that time. Since what is being challenged is the maintenance of each safeguard measure, it is of no

[1868] In our view, the state of scientific knowledge is one example of a circumstance which is relevant to the assessment of risks and which is subject to change over time. Indeed, evolution of science may result in new and/or better scientific evidence becoming available, and such evidence may have an effect on the continued relevance and validity of the conclusions of an existing risk assessment.

[1869] It should be noted in this context that, in our view, a completed risk assessment which meets the definition of Annex A(4) and is consistent with the requirements of Articles 5.2 and 5.3 of the *SPS Agreement* would not cease to satisfy that definition or these requirements merely because there was a change in relevant circumstances and that change affected the continued relevance of that risk assessment. To provide a simple example: A risk assessment within the meaning of Annex A(4) which has not been updated over time continues to be a risk assessment within the meaning of Annex A(4). However, as we have said, such a risk assessment may no longer be "appropriate to the circumstances" in the sense of Article 5.1.

[1870] Appellate Body Report, *EC – Hormones*, para. 129.

[1871] Panel Report, *Japan – Apples*, para. 7.12.

particular importance whether a specific risk assessment which is claimed to serve as a basis for a safeguard measure was performed before or after the adoption of that safeguard measure. What matters is that the relevant risk assessment was appropriate to the circumstances existing at the time this Panel was established. In the light of this, in our analysis of whether there are risk assessments on which individual safeguard measures were based at the relevant time, we will consider assessments which were carried out before these measures were adopted as well as assessments which were carried out after these measures were adopted.

*(ii) Austria – T25 maize*

7.3035 The Panel commences its analysis of individual safeguard measures with Austria's measure on T25 maize. The first issue we will address is whether the documents Austria relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3036 We first recall that in the Reasons document, Austria presented various concerns in support of its safeguard measure on T25 maize, including, *inter alia*, the fact that the product had not been examined under realistic conditions as far as the use of herbicide is concerned, and that no monitoring programme was foreseen to assess the long-term effects of T25 maize.[1872] With respect to its concern regarding the assessment of long-term effects, Austria invoked the need to protect sensitive areas, referring to a study by Hoppichler entitled "Concepts of GMO-Free Environmentally Sensitive Areas", which was commissioned by the Austrian Federal Ministry of Women's Affairs and Consumer Protection (hereafter the "Hoppichler study ").[1873] This study appears to be the only scientific evidence which Austria relied on at the time of adoption of its safeguard measure.

7.3037 As also noted earlier, Austria invoked further concerns in the January 2004 document, namely, with respect to risks related to allergenicity and toxicity, the potential environmental impact of *Bt* toxin as well as antibiotic resistance marker genes.[1874] In relation to the January 2004 document, we recall that our task is to assess whether the Austrian safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that Austria's safeguard measure was not based on a risk assessment in August 2003. However, we note that one of the studies mentioned by Austria in the January 2004 document was published in March 2003, and we therefore take it into account. The study in question is a joint study by the Federal Ministry of the Environment ("Umweltbundesamt GmbH") and IFF/IFZ – Inter-University Research Centre for Technology, Work and Culture, entitled "*Toxicology and Allergology of GM Products: Investigations into practice and recommendations on the standardization of risk assessment of genetically modified food*" (hereinafter the "March 2003 document").[1875]

7.3038 Having identified the documents which Austria relies on to justify its safeguard measure, we can now go on to determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

[1872] Exhibit EC-160/At. 3.
[1873] Exhibit EC-160/At. 5.
[1874] Exhibit EC-158/At. 30.
[1875] Exhibit EC-158/At. 41_trans.

7.3039 We recall that Austria justified its safeguard measures by reference to concerns relating to the spread of pollen to cultivated surrounding fields, long-term ecological effects, the potential development of antibiotic resistance and allergenicity and toxicity. We have determined that to the extent Austria's measure is applied to address concerns over the spread of pollen to cultivated surrounding fields, long-term ecological effects and the development of antibiotic resistance, it falls within the scope of Annex A(1)(a) and/or (d) of the *SPS Agreement*. The first clause of Annex A(4) to the *SPS Agreement* provides the following definition for the "risk assessment" to be carried out for measures which have purposes falling within the scope of Annex A(1)(a) or (d):

> "*Risk assessment* – The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences."

7.3040 Based on this definition, the Appellate Body in *Australia – Salmon* found that a risk assessment must:[1876]

> "1) *identify* the diseases [or pests] whose entry, establishment or spread a Member wants to prevent on its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
>
> 2) evaluate the *likelihood* of entry, establishment or spread of these diseases [or pests], as well as the associated potential biological and economic consequences; and
>
> 3) evaluate the likelihood of entry, establishment or spread of these diseases [or pests] *according to the SPS measures which might be applied*."

7.3041 We begin our analysis of Austria's Reasons document. In this document, Austria alleges that T25 maize was not examined under realistic conditions of the use of the herbicide and of correspondent agricultural practices; that there was no monitoring programme to assess the long-term effects of biotech plants and herbicides, and in particular with respect to the protection of environmentally sensitive areas; that there were no special measures to monitor the possible spread of pollen to fields in the surroundings cultivated with conventional maize (co-existence); and that regional ecological aspects were not differentiated as far as resistance development is concerned. We note that the Reasons document highlights concerns related to the lack of a monitoring programme for possible long term environmental impacts associated with herbicide use on GM plants and the spread of pollen from GM cultivated fields to fields in surrounding areas. Regarding the concern over the spread of pollen, the Reasons document includes references to possibilities of associated risks, but it does not provide an evaluation of the likelihood of such risks occurring. For example, the document states that the spread of pollen is "mostly regarded as safe."[1877] On the other hand, the Reasons document does not make explicit claims regarding the risks associated with the long-term environmental impacts of herbicide use in conjunction with GM crops in ecologically sensitive areas, but rather refers to the Hoppichler study for discussion of these risks.

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[1876] Appellate Body Report, *Australia-Salmon*, para. 121 (bracketed text added).
[1877] Exhibit EC-160/At. 3.

7.3042 The Hoppichler study focuses on the protection of environmentally-sensitive areas. Based on the evidence submitted to us[1878], we understand that Austria is seeking to prevent the cultivation and other uses of GMOs on its territory due to possible long-term ecological risks associated with GMOs, particularly in fragile areas. In addition, the study argues that "multiple releases and the marketing of GMOs are irreversible processes, and [...] products of organic agriculture will also contain GMOs even if they are produced strictly on the basis of organic guidelines."[1879]

7.3043 In considering the Hoppichler study, we recall that the Commission requested the SCP to analyse the information provided by Austria, including the aforementioned study, in order to determine whether this information may "constitute relevant scientific evidence, which would cause the SCP to consider that this product constitutes a risk to human health and the environment."[1880] In response, the SCP prepared an opinion which notes that the Hoppichler study "does not contain any new scientific information which is relevant to the original scientific risk assessment that [the SCP] published in 1998. Rather the document contains arguments for the establishment of GMO-free environmentally-sensitive areas and summarises surveyed opinions of people who may be confronted professionally with any environmental effects of the release of GMOs." We understand this statement to indicate that the SCP did not view this study as a risk assessment.

7.3044 We also note that the Hoppichler study does not indicate relative probability of the potential risks it identifies, but rather makes reference to possibilities of risks or simply to the inability to determine probabilities. For example, the document states that "there are possibilities of direct risks which can be assessed within some limits according to the status of science and technology".[1881] In addition, the study cites two analyses regarding environmental risk assessment of releasing GMOs. A quote from the first analysis indicates that "the ecological impact of transgenic grasses *may be* pervasive" (emphasis added).[1882] The second analysis is said to demonstrate that "the contamination of natural gene pools through synthetic genes is incalculable in principle in predictive risk assessment".[1883] This statement highlights the lack of estimated risk associated with gene flow from GMOs.

7.3045 Regarding these references to possibilities of risks, we recall that the Appellate Body in *Australia – Salmon* stated that:

> "[I]t is not sufficient that a risk assessment conclude that there is a *possibility* of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment of this type must evaluate the 'likelihood' i.e., the 'probability', of entry, establishment or spread of diseases and associated biological and economic consequences."[1884]

7.3046 Given the lack of evaluation of likelihood in the Hoppichler study, we consider that the study does not meet the definition of a risk assessment as provided in Annex A(4), and therefore does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

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[1878] We note that the European Communities provided a summary of the Hoppichler study in English (Exhibit EC-160/At. 5).
[1879] Exhibit EC-160/At. 5, p. 8.
[1880] Exhibits US-56; CDA-77; ARG-45 and -46.
[1881] Exhibit EC-160/At. 5, p. 4.
[1882] Exhibit EC-160/At. 5, p. 4.
[1883] Exhibit EC-160/At. 5, p. 4.
[1884] Appellate Body Report, *Australia – Salmon*, paras. 123-124.

7.3047 We now turn to determine whether any of the relevant documents relied on by Austria contains a risk assessment with regard to Austria's concerns over the development of antibiotic resistance and allergencity and toxicity. We recall in this respect our earlier finding that to the extent Austria's measure is applied to address such concerns, it falls within the scope of Annex A(1)(b) the *SPS Agreement*. The second clause of Annex A(4) to the *SPS Agreement* provides the following definition for the "risk assessment" to be carried out for measures which have purposes falling within the scope of Annex A(1)(b):

> "*Risk assessment*: [...] the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

7.3048 We note that, unlike for the definition of risk assessment contained in the first clause of Annex A(4), WTO jurisprudence provides little guidance on the meaning of key concepts contained in the definition provided in the second clause. The Appellate Body merely observed in this respect that the first clause is substantially different from the second clause, and that the second clause requires "only" the evaluation of the "potential" for adverse effects on human or animal health arising from the presence of certain substances in foods, whereas the first clause requires an evaluation of the "likelihood" of entry, establishment or spread of a pest or disease and of the associated biological and economic consequences.[1885] We note that the dictionary defines the term "potential" as "the possibility of something happening [...] in the future".[1886]

7.3049 In this context, one relevant document to be examined is the Austrian study on toxicology and allergology of biotech products of March 2003. This study reviews the assessment under Regulation 258/97 of toxic and allergenic risks of food containing or consisting of GMOs. The objective of the study was to investigate risk assessment practices for food derived from biotech plants, and to make proposals to "concretise and standardise the toxicological and allergological risk assessment."[1887] We consider that this study evaluates risk assessment *procedures*, and not the potential for adverse effects on human or animal health arising from the consumption of specific foods containing or consisting of GMOs. We therefore think that the March 2003 study does not meet the definition of a risk assessment as provided in Annex A(4).

7.3050 Regarding Austria's concern about the development of antibiotic resistance, we recall that this concern was raised in the January 2004 document.[1888] However, none of the supporting documents which were provided to the Panel contains a discussion of risks associated with this specific concern in the context of the product at issue. The Austrian study on toxicology and allergology of biotech products of March 2003 reviews procedures for the assessment of risks of food containing or consisting of GMOs; the issue of antibiotic resistance is not included in the analysis. Thus, we are not aware of any pre-August 2003 document which addresses the issue of antibiotic resistance and which meets the definition of a risk assessment provided in Annex A(4).

7.3051 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Austria to justify its safeguard measure are not in themselves risk assessments within the meaning of Annex A(4) and Article 5.1.

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[1885] Appellate Body Report, *Australia – Salmon*, footnote 69.

[1886] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1120.

[1887] Exhibit EC-158/At. 41, p. 19.

[1888] Exhibit EC-158/At. 30.

7.3052 In connection with the documents relied on by Austria, we should also note the European Communities' argument that Austria's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. According to the European Communities, the phrase "as appropriate to the circumstances" makes it clear that Members have a certain degree of flexibility in meeting the requirements of Article 5.1.[1889] The European Communities submits that the circumstances in the case of the Austrian safeguard measure include the fact that, from Austria's perspective, relevant scientific evidence was or is insufficient.

7.3053 We need not determine whether relevant scientific evidence was or is insufficient for Austria, and if so, whether this would be a relevant circumstance. Even if this were the case, the flexibility which the phrase "as appropriate to the circumstances" may in some situations provide does not relieve Austria from the requirement in Article 5.1 to base its safeguard measure on a risk assessment which meets the definition of Annex A(4).[1890] All of the Annex A(4) definition of the term "risk assessment" which are applicable to Austria's safeguard measure, must, in our view, be met. It is useful to recall in this respect that the Appellate Body in *Australia – Salmon* observed that an evaluation of the likelihood of entry, establishment or spread of a pest could be done both quantitatively and qualitatively.[1891] Moreover, in circumstances where there is little available scientific evidence, the phrase "as appropriate to the circumstances" may provide a measure of flexibility in terms of how (but not whether) the applicable elements of the Annex A(4) definition, including the likelihood evaluation, are satisfied. In the case at hand, we have answered in the negative the question of whether the documents which Austria relied on satisfy the applicable elements of the Annex A(4) definition of the term "risk assessment". Therefore, we see no need to examine further the European Communities' argument in relation to the phrase "as appropriate to the circumstances".

7.3054 We have found above that none of the documents relied on by Austria constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by Austria which constitutes a risk assessment for T25 maize. The document in question is the "[r]isk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1892] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[1893] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3055 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". We also recall in this regard that the SCP confirmed its original risk assessment after reviewing the information relied on by Austria. In the light of this, and in view of our findings below with regard to whether the Austrian safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

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[1889] In support of its statement, the European Communities refers to the Appellate Body report on *EC – Hormones*, para. 129.

[1890] We note in this context the statement by the panel in *Australia – Salmon* to the effect that the phrase "as appropriate to the circumstances" "cannot [...] annul or supersede the substantive obligation resting on Australia to base the sanitary measure in dispute [...] on a risk assessment". Panel Report, *Australia – Salmon*, para. 8.57.

[1891] Appellate Body Report, *Australia – Salmon*, para. 124.

[1892] EC reply to Panel question No. 107.

[1893] Exhibits EC-160/At. 2; CDA-75 and 87; US-56 (referencing original SCP assessment); ARG-45 and 46 (referencing original SCP assessment).

"Based on"

7.3056 As noted, it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP. In our analysis below, we will examine whether, at the time of establishment of this Panel, the Austrian safeguard measure was "based on" either of these risk assessments.

7.3057 The European Communities presents two main arguments to support its assertion that the Austrian safeguard measure is based on a risk assessment pursuant to Article 5.1. The first argument of the European Communities is that responsible and representative governments may act either on the basis of mainstream scientific opinion or on the basis of a divergent scientific view. Regarding Austria's safeguard measure on T25 maize, the European Communities submits that Austria acted on the basis of new scientific information, which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment.

7.3058 The Panel notes that in *EC - Hormones*, the Appellate Body observed that a "[r]isk assessment could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view".[1894] It then went on to state that "responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety."[1895]

7.3059 It is important to recall that this statement related to a hypothetical situation where divergent views were expressed as part of, and in, the same risk assessment. In the case at hand, we are not aware, and have not been made aware, of any divergent views that would be expressed in the risk assessments of the lead CA and SCP concerning T25 maize. Therefore, we are presented here with a situation that is different from that described by the Appellate Body in *EC – Hormones*. Furthermore, we note that the contributions of the Panel's experts do not support the view that the potential risks arising from the deliberate release of T25 maize and the other biotech products subject to this dispute can be considered to be risks that are "life-threatening in character" or that "constitute a clear and imminent threat to public health and safety".[1896]

7.3060 Where a given risk assessment sets out a divergent opinion[1897] and this opinion comes from qualified and respected sources, it can be reasonably said that an SPS measure which reflects the divergent opinion is "based on" the risk assessment in question inasmuch as the divergent opinion is expressed in that risk assessment. In contrast, where a given risk assessment sets out a single opinion, it cannot be reasonably said that an SPS measure is "based on" *that* risk assessment if the relevant SPS measure reflects a divergent opinion which is not expressed in the risk assessment in question. *Ex hypothesi*, the opinion expressed in that risk assessment would not "sufficiently warrant", or "reasonably support", the SPS measure taken.

7.3061 In the case of the Austrian safeguard measure, the European Communities asserts that new scientific information became available and that this new information justified Austria's differing

[1894] Appellate Body Report, *EC - Hormones*, para. 194.
[1895] Appellate Body Report, *EC - Hormones*, paras. 193-194.
[1896] *Ibid.*
[1897] We use the term "divergent opinion" or "divergent assessment" to refer to an opinion or assessment which argues for, and supports, a significantly different overall conclusion.

assessment of the risks. Even assuming this were the case, however, this would not alter the fact that we are unaware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP. Therefore, it would be clear that, on the date of establishment of this Panel, Austria's safeguard measure would not have been based on these existing risk assessments, but on its own modified version of these assessments, namely, its divergent assessment.

7.3062 Even if the alleged divergent assessment by Austria in a number of respects did not depart from the existing risk assessments, Austria's safeguard measure could not, for that reason alone, be considered to be based on these risk assessments if these assessments reached a different overall conclusion. To be clear, we are not suggesting that Members cannot rely in part on an existing risk assessment which sets out a single opinion. But to the extent they disagree with some or all of the conclusions contained in such an assessment, it would in our view be necessary for Members to explain, by reference to the existing assessment, how and why they assess the risks differently, and to provide their revised or supplemental assessment of the risks. The European Communities or Austria did not do so in relation to the safeguard measure on T25 maize.

7.3063 Since we are unable to accept the European Communities' first argument in support of its view that the Austrian safeguard measure is based on the risk assessments conducted by the lead CA and the SCP, we must go on to examine the European Communities' second argument. The second argument of the European Communities is that the risk assessment carried out before Community-wide marketing approval was given, can serve, at least temporarily, as a basis for both the Community-wide marketing approval and Austria's provisional safeguard measure. In other words, the European Communities contends that the same risk assessment can "sufficiently warrant", or "reasonably support", more than one type of SPS measure, or, as the European Communities puts it, one and the same risk assessment may justify "divergent responses by equally responsible and representative governments".[1898]

7.3064 As a general matter, the Panel agrees with the European Communities that a particular risk assessment might conceivably serve as a basis for different types of SPS measures. Indeed, there may be a range of measures that may be rationally related to a given risk assessment, at least in cases where a risk is determined to exist.[1899] In the present case, the risk assessments conducted by the lead CA and by the SCP with regard to T25 maize were favourable.[1900] These assessments concluded that there was no evidence that T25 maize presents any greater risk to human health or the environment than its conventional (non-biotech) counterpart. Yet, the safeguard measure which Austria allegedly adopted on the basis of these risk assessments provides for a complete prohibition of the product.[1901] In our view, the favourable findings of the risk assessments in question do not naturally lead to the conclusion that what is arguably the strictest type of SPS measure, *i.e.*, a complete prohibition, was warranted in Austria's case to protect human health and the environment. To the contrary, these findings strongly suggest that this type of measure was not sufficiently warranted.

7.3065 The European Communities asserts that each of the safeguard measures at issue in this dispute is based on the precautionary principle. We would agree that the fact that a Member has

[1898] *See* EC reply to Panel question No. 107.

[1899] While there may be a variety of SPS measures that would be rationally related to a given risk assessment, some of these measures may be inconsistent with Article 5.6 of the *SPS Agreement*. In other words, there may be SPS measures which are rationally related to a risk assessment, but more trade-restrictive than required to achieve a Member's appropriate level or protection.

[1900] Exhibits EC-160/At. 2; CDA-75 and 87; US-56 (referencing original SCP risk assessment); ARG-45 and 46 (referencing original SCP risk assessment).

[1901] As we have noted, the prohibition is subject to an exception which applies in cases where the products are meant to be immediately re-exported after handling and repackaging (Exhibit EC-160/At. 3_trans).

decided to follow a precautionary approach could have a bearing on a panel's assessment of whether an SPS measure is "based on" a risk assessment as required by Article 5.1. We consider that if there are factors which affect scientists' level of confidence in a risk assessment they have carried out[1902], a Member may in principle take this into account in determining the measure to be applied for achieving its appropriate level of protection from risks.[1903] Thus, there may conceivably be cases where a Member which follows a precautionary approach, and which confronts a risk assessment that identifies uncertainties[1904] or constraints, would be justified in applying (i) an SPS measure even though another Member might not decide to apply any SPS measure on the basis of the same risk assessment, or (ii) an SPS measure which is stricter than the SPS measure applied by another Member to address the same risk. However, even if a Member follows a precautionary approach, its SPS measures need to be "based on" (*i.e.*, "sufficiently warranted" or "reasonably supported" by) a risk assessment. Or, to put it another way, such an approach needs to be applied in a manner consistent with the requirements of Article 5.1.[1905]

7.3066 In the case of Austria's safeguard measure on T25 maize, the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, much less explained why, in view of any such uncertainties or constraints, Austria's prohibition is warranted by the relevant risk assessments. Therefore, the European Communities' argument about the precautionary approach does not persuade us that Austria's safeguard measure is "sufficiently warranted" by the favourable risk assessments which were performed with regard to T25 maize. In other words, if Austria's safeguard measure reflects a precautionary approach, we consider, based on the evidence before us, that Austria did not implement that approach in a manner consistent with the requirements of Article 5.1.

7.3067 We note the European Communities' argument that "based on" does not mean "conform to". To the extent the European Communities means to argue that Members are free to adopt any kind of SPS measure provided there exists a risk assessment for the product subject to the SPS measure, we

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[1902] *E.g.*, a limited body of relevant scientific evidence may be such a factor.

[1903] This view is consistent with risk assessment techniques established by relevant international organizations. For instance, the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* state that "[t]he report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors". Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (adopted in June/July 2003), Section III, Codex Procedural Manual, 14th edition, 2004, para. 25. Along similar lines, the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* state that "[r]isk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties". Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (adopted in June/July 2003), CAC/GL 44-2003, para. 18. Similarly, the IPPC's ISPM #11 (2001) states in relevant part that "[t]he uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option". IPPC, ISPM #11: *Pest Risk Analysis for Quarantine Pests*, April 2001, para. 3. The quoted passage stayed the same in the 2004 version of ISPM #11, which applies specifically to living modified organisms.

[1904] We are not referring here to the theoretical uncertainty which inevitably remains because science can never provide absolute certainty that a product will never have adverse effects on human health or the environment. The Appellate Body has made it clear that this theoretical uncertainty is not the kind of risk which is to be assessed under Article 5.1. Appellate Body Report, *EC – Hormones*, para. 186.

[1905] We recall that according to the Appellate Body, the precautionary principle "has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement". Appellate Body Report, *EC – Hormones*, para. 124.

disagree. It is correct that the Appellate Body in *EC – Hormones* has said that the expression "based on" as it appears in Article 3.1 of the *SPS Agreement*[1906] does not mean "conform to".[1907] However, the Appellate Body also said in *EC – Hormones* that in the specific context of Article 5.1, the expression "based on" should be interpreted to mean "sufficiently warranted by", "reasonably supported by" or "rationally related to".[1908] As we have said, in the case of Austria's safeguard measure on T25 maize, there exists no apparent rational relationship between that measure, which imposes a complete prohibition, and risk assessments which found no evidence that T25 maize presents any greater risk to human health or the environment than its conventional (non-biotech) counterpart.[1909] At any rate, if we were to allow Austria effectively to ignore favourable risk assessments, we would turn these assessments into documents without any substantive importance and the conduct of these assessments into a mere formality. Yet, the requirement in Article 5.1 to "base" an SPS measure on a risk assessment is plainly a substantive requirement, and not simply a formal requirement to accompany an SPS measure by a risk assessment.[1910]

7.3068 In view of the foregoing considerations, while not rejecting the European Communities' second argument generally, we do not agree with the European Communities that Austria's safeguard measure can be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize.

7.3069 Accordingly, since we are of the view that Austria's safeguard measure cannot be considered to be "based on" the existing (original) risk assessments, and recalling also that no other risk assessment which might reasonably support Austria's safeguard measure has been provided to us, we find that the Austrian measure prohibiting the placing on the market of T25 maize is not based on a risk assessment pursuant to Article 5.1.[1911]

Overall conclusions

7.3070 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment.

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[1906] Article 3.1 states in relevant part that "Members shall base their [SPS] measures on international standards, guidelines or recommendations, where they exist [...]".

[1907] Appellate Body Report, *EC - Hormones*, para. 166.

[1908] *Ibid.*, para. 193.

[1909] We note that the Appellate Body in *EC – Hormones* confronted a comparable situation. Specifically, the Appellate Body found that scientific reports which concluded that the use of certain hormones for growth promotion purposes was safe did not rationally support an import prohibition maintained by the European Communities. Appellate Body Report, *EC - Hormones*, paras. 196-197.

[1910] We note that the Appellate Body in *EC – Hormones* also characterized the requirement that an SPS measure be "based on" a risk assessment as a "substantive requirement". Appellate Body Report, *EC - Hormones*, para. 193.

[1911] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment.

7.3071 In view of our findings in the previous paragraph with regard to DS291 (United States), DS292 (Canada) and DS293 (Argentina), it is necessary to examine, in addition, whether the Austrian safeguard measure on T25 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Austrian safeguard measure on T25 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(iii) Austria – Bt-176 maize*

7.3072 The Panel turns to its analysis of Austria's measure on Bt-176 maize. The first issue we will address is whether the documents Austria relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3073 We recall from the Reasons document that Austria's concerns with respect to Bt-176 maize were related in particular to the issues of gene transfer (development of antibiotic resistance) and the development of resistance to *Bt* toxin.[1912] With respect to each of these concerns, Austria presented the scientific reasons for its decision to prohibit Bt-176 maize.[1913]

7.3074 We note that Austria provided additional scientific evidence to the Commission in May 1997 in support of its safeguard measure on Bt-176 maize.[1914] In particular, Austria provided two studies concerning the development of resistance to *Bt* toxin arising from the circumstance that transgenic crops producing insecticidal proteins from *Bt* are being grown commercially (hereafter the "March and April 1997 studies").[1915]

[1912] Exhibit EC-158/At. 7.

[1913] We note that Austria's Reasons document makes reference to a number of scientific studies in support of its safeguard measure. However, since these studies were not submitted to the Panel as evidence, we cannot determine whether any of these studies constitutes in itself a risk assessment on which the safeguard measure might be based. We do note, however, that many of these studies predate the original EC risk assessment and would presumably have been known to and taken into account in the context of that risk assessment.

[1914] Exhibit EC-158/At. 10.

[1915] Exhibit EC-158/Ats. 11-12.

7.3075 Furthermore, in the January 2004 document, Austria invoked recent scientific findings concerning risks related to allergenicity and toxicity, the potential environmental impact of *Bt* toxin, including effects on non-target organisms, as well as antibiotic resistance marker genes.[1916] In relation to the January 2004 document, we recall that our task is to assess whether the Austrian safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that Austria's safeguard measure was not based on a risk assessment in August 2003. However, we note that one of the studies mentioned by Austria in the January 2004 document was published in March 2003, and we therefore take it into account. The study in question is a joint study by the Federal Ministry of the Environment ("Umweltbundesamt GmbH") and IFF/IFZ – Inter-University Research Centre for Technology, Work and Culture, entitled "*Toxicology and Allergology of GM Products: Investigations into practice and recommendations on the standardization of risk assessment of genetically modified food*" (hereinafter the "March 2003 document").[1917]

7.3076 Having identified the documents which Austria relies on to justify its safeguard measure, we can now go on to determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*. As with Austria's safeguard measure for T25 maize, given the concerns raised by Austria in the context of Bt-176 maize, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for Austria's measure on Bt-176 maize.

7.3077 We begin our analysis with Austria's Reasons document. We note that the Reasons document highlights concerns related to the development of antibiotic resistance and the impacts of the development of insect resistance to Bt toxin. Furthermore, we note that Austria makes reference in the Reasons document to the original risk assessments undertaken by the Scientific Committee for Food (SCF), the Scientific Committee for Animal Nutrition (SCAN) and the Scientific Committee on Pesticides (SCPE). While noting that all the scientific comments and arguments presented in the opinions of these scientific committees are "valid and well taken"[1918], Austria asserts that new scientific results raise questions about the possibility of a conclusive evaluation of the mechanism of gene transfer, as well as the development of resistance to Bt toxin. With regard to these new scientific results, Austria notes that " possible risks are very hard to assess and should be avoided at the present state of the scientific discussion."[1919] In a similar vein, the Reasons document states that "[t]here are adequate maize-products already available which do not comprise these restrictions and by this there is no reason to accept risks which are difficult to assess".[1920] Elsewhere, the Reasons document states that "[t]he impact of a transfer of the *bla* gene to bacteria of humans or animals can not be fully evaluated".[1921] These statements serve to demonstrate that Austria did not "assess" the alleged risks identified in the Reasons document. Therefore, we do not consider that the Reasons document constitutes an "assessment" of risks within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.

7.3078 We now turn to the two scientific studies that Austria provided to the Commission in May 1997 in support of its safeguard measure on Bt-176 maize.[1922] These studies focused on the

[1916] Exhibit EC-158/At. 30.
[1917] Exhibit EC-158/At. 41_trans.
[1918] Exhibit 158/At. 7, p. 5.
[1919] *Ibid.*
[1920] *Ibid*.
[1921] Exhibit 158/At. 7, p. 6.
[1922] Exhibit EC-158/At. 10.

development of resistance to Bt toxin due to the commercial production of transgenic Bt crops (studies published in the National Academy of Science from March and April 1997).[1923] Both of these studies examine the mechanism through which insects develop resistance to Bt toxin. The first study describes a technique for estimating the likelihood that a particular population of insects would develop resistance to Bt toxin, while the second uses genetic analysis to show that a single insect gene can confer resistance to several different strains of the Bt toxin. The first study focuses on insects feeding on Bt cotton; the second examines the genetics underlying the evolution of resistance through feeding studies of insects on Bt toxins in dust form. While the results of these studies may be of relevance to the assessment of the risks of the potential development of resistance to Bt-176 maize, neither study assesses the likelihood of this risk. For this reason, we do not consider that the March 1997 and April 1997 studies meet the definition of a risk assessment as provided in Annex A(4). We therefore consider that these studies cannot be considered risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3079 We recall that the European Communities provided as evidence a study by Austria on toxicological and allergological risks related to biotech products (the March 2003 document).[1924] As we noted above with respect to T25 maize, we consider that this study evaluates risk assessment *procedures*, and not the potential for adverse effects on human or animal health arising from the consumption of specific foods containing or consisting of GMOs.[1925] We therefore think that this March 2003 study does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3080 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Austria to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3081 Furthermore, in connection with the documents relied on by Austria, we should also note the European Communities' argument that Austria's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Austrian safeguard measure include the fact that, from Austria's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3052-7.3053 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3082 We have found above that none of the documents relied on by Austria with regard to its safeguard measure on Bt-176 maize constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by Austria which constitutes a risk assessment for Bt-176. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1926] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or any of the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal

[1923] Exhibit EC-158/Ats. 11-12.
[1924] *See supra*, para. 7.3037.
[1925] *See supra*, para. 7.3049.
[1926] EC reply to Panel question No. 107.

Nutrition (SCAN) or the SCF.[1927] In any event, we have noted above that it is not in dispute that all of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3083 In addition, we recall that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the Austrian safeguard measure on Bt-176 maize is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3084 We now turn to the question of whether, at the time of establishment of this Panel, the Austrian safeguard measure on Bt-176 maize was "based on" either the risk assessment of the lead CA or any of those conducted by the SCPE, the SCAN or the SCF.[1928]

7.3085 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Austria's safeguard measure on Bt-176 maize and the risk assessment performed by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF in relation to Bt-176. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF with regard to Bt-176 maize;

(b) the European Communities or Austria did not explain, by reference to these risk assessments, how and why Austria assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Austria's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Austria's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Bt-176 maize will give rise to any adverse effects on human or animal health and the environment.

7.3086 Thus, in view of our conclusion that Austria's safeguard measure on Bt-176 maize cannot be considered to be "based on" the risk assessment performed by the lead CA or the risk assessments

[1927] Exhibits EC-158/Ats. 1-3; EC-158/At. 4; EC-158/At. 5; EC-158/At. 6.

[1928] As noted, we must examine as part of our analysis whether the safeguard measure is based on any of those risk assessments, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or those conducted by the SCPE, the SCAN or the SCF.

which were conducted by the SCPE, the SCAN or the SCF in relation to Bt-176 maize, and recalling the fact that no other risk assessment which might reasonably support Austria's safeguard measure has been provided to us, we find that the Austrian safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1929]

Overall conclusions

7.3087 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment.

7.3088 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether the Austrian safeguard measure on Bt-176 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Austrian safeguard measure on Bt-176 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(iv) Austria – MON810 maize*

7.3089 We now turn to the analysis of Austria's measure on MON810 maize. The first issue we will address is whether the documents Austria relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3090 We recall from the Reasons document that Austria's concerns with respect to MON810 maize were related in particular to undesired effects on non-target organisms and the development of resistance to *Bt* toxin in insects.[1930] In relation to each of these concerns, Austria refers to the results of recent scientific studies. We note that only the following scientific studies invoked by Austria in the Reasons document in support of its safeguard measure on MON810 maize were submitted to the Panel:

[1929] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[1930] Exhibit EC-159/At. 3.

(i) Study by Losey (1999), "Transgenic pollen harms monarch larvae"[1931];

(ii) Study by Hilbeck *et al.* (1998), "Toxicity of Bacillus thuringiensis Cry1Ab Toxin to the Predator Chrysoperla carnea (Neuroptera: Chrysopidae)"[1932];

(iii) Study by Hilbeck *et al.* (1998), "Effects of transgenic Bacillus thuringiensis corn-fed prey on mortality and development time of immature Chrysoperla carnea (Neuroptera: Chrysopidae)"[1933].

7.3091 Furthermore, we recall that in the January 2004 document, Austria invoked scientific findings concerning risks related to allergenicity and toxicity, the potential environmental impact of *Bt* toxin, as well as antibiotic resistance marker genes.[1934] In relation to the document of January 2004, we recall that our task is to assess whether the Austrian safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that Austria's safeguard measure was not based on a risk assessment in August 2003. However, we note that one of the studies mentioned by Austria in the January 2004 document was published in March 2003, and we therefore take it into account. The study in question is a joint study by the Federal Ministry of the Environment ("Umweltbundesamt GmbH") and IFF/IFZ – Inter-University Research Centre for Technology, Work and Culture, entitled "*Toxicology and Allergology of GM Products: Investigations into practice and recommendations on the standardization of risk assessment of genetically modified food*" (hereinafter the "March 2003 document").[1935]

7.3092 As with Austria's safeguard measures on T25 maize and Bt-176 maize, given the concerns raised by Austria in the context of MON810 maize, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* provide definitions for the "risk assessment" to be carried out for Austria's measure on MON810 maize.

7.3093 We begin our analysis with Austria's Reasons document. In this document, Austria points to new scientific evidence which, according to Austria, raises uncertainty with respect to the potential risks related to MON810 maize, in particular regarding the effects on non-target organisms and the development of resistance in insects. According to Austria, this new scientific evidence raises doubts with regard to the safety of MON810 maize for human health or the environment.

7.3094 However, nothing in the Reasons document indicates that Austria carried out a new assessment of the alleged risks in the light of the scientific evidence mentioned by Austria. We recall in this connection that a risk assessment must evaluate the likelihood or probability of particular risks, or evaluate the potential for adverse effects on animal health arising from the presence of certain substances in food, beverages or feedstuffs.[1936] The Reasons document refers to possibilities of risks arising in respect of MON810 maize, but it does not itself evaluate the potential for adverse health effects or the likelihood of the risk of establishment, entry or spread of a pest. For example, Austria notes that reservations concern the "[p]ossible undesired effects of the Bt toxin on non-target

[1931] Exhibit EC-158/At. 24.
[1932] Exhibit EC-158/At. 26.
[1933] Exhibit EC-158/At. 27.
[1934] Exhibit EC-158/At. 30.
[1935] Exhibit EC-158/At. 41_trans.
[1936] We note that "evaluate" is defined as "form an idea of the amount, number or value of; assess", *Concise Oxford English Dictionary*, Eleventh Ed. 2004, p. 493.

organisms and the possible development of resistance in insects".[1937] The document highlights studies of undesired effects on non-target organisms related to the consumption of Bt maize but does not itself make an evaluation of the potential for adverse health effects or the likelihood of these undesired effects occurring in the event that MON810 maize were to be introduced.[1938] The Reasons document also identified one study which noted that "further effects on the food chain [of consumption of Bt pollen by monarch butterflies] are possible."[1939] Yet, there is no evaluation of the potential for adverse health effects or the likelihood of such effects occurring.

7.3095 Furthermore, we note that with respect to one of the risks identified in the Reasons document, namely the development of resistance to Bt toxin in insects, the Reasons document states that "[t]he risk for related groups of insects [...] cannot be assessed conclusively based on the available data."[1940] This statement further confirms that Austria did not "evaluate" or "assess" the alleged risk.

7.3096 Accordingly, we are of the view that the Reasons document does not meet the definition of a risk assessment as provided in Annex A(4). We therefore consider that the Reasons document cannot be considered a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3097 We now turn to the scientific studies referred to by Austria in its Reasons document. Each of these studies describes aspects of Bt toxin impacts on insects. The study by Losey, entitled "Transgenic pollen harms monarch larvae"[1941], describes results from a laboratory experiment in which monarch butterfly caterpillars were fed Bt maize pollen. The study focuses on a variety of Bt maize other than MON810 maize. Furthermore, while the Losey study notes that results on larvae consumption and growth rates have "potentially profound implications for the conservation of monarch butterflies" there is no attempt to evaluate these potential implications, rather the study notes that the experimental results point to possible environmental outcomes. For example, in arguing that monarch butterfly caterpillars are at risk from the production of Bt maize, the study states that "[t]he large land area covered by corn in this region *suggests* that a substantial portion of available milkweeds *may be* within range of corn pollen deposition".[1942] Hence, we do not consider that the Losey study in itself constitutes a risk assessment within the meaning of either the first or the second clause of Annex A(4) and Article 5.1.

7.3098 The second study, by Hilbeck *et al.*, on "[t]oxicity of Bacillus thuringiensis Cry1Ab Toxin to the Predator Chrysoperla carnea (Neuroptera: Chrysopidae)"[1943] described a feeding study in which insects were fed a liquid diet containing Bt toxins, rather than being fed Bt plants directly. Thus, we do not consider that this study evaluated the potential for adverse effects associated with the insects eating MON810 maize plants. In addition, in its conclusion it notes that "trials investigating predation efficiency and predator performance under field conditions are necessary before conclusions regarding the potential ecological relevance of the results presented [...] can be drawn."[1944] Hence, like the Losey study, the study by Hilbeck *et al.* does not evaluate the likelihood of an outcome in the field. Accordingly, as with the Losey study, we do not consider that the Hilbeck *et al*. study in itself constitutes a risk assessment within the meaning of either the first or the second clause of Annex A(4) and Article 5.1, although we accept that it may be of relevance for a risk assessment.

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[1937] Exhibit EC-159/At. 3_trans p. 5.
[1938] Exhibit EC-159/At. 3_trans pp. 5-6.
[1939] Exhibit EC-159/At. 3_trans p. 6.
[1940] Exhibit EC-159/At. 3_trans p. 8.
[1941] Exhibit EC-158/At. 24.
[1942] Exhibit EC- 158/At. 24 (emphasis added).
[1943] Exhibit EC-158/At. 26.
[1944] Exhibit EC-158/26 p. 7.

7.3099 The third study, also by Hilbeck *et al.*, concerns "[e]ffects of transgenic Bacillus thuringiensis corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae)".[1945] This study used a maize hybrid containing a gene from *Bacillus thuringiensis*. The study provides information regarding the impact on non-maize eating insects of eating herbivorous insects raised on Bt maize and thus is aimed at evaluating non-target impacts of Bt crop cultivation. While this study concludes that, in this experiment, differences in mortality exist for insect predators fed prey raised on Bt versus non-Bt maize, the study notes that "[n]o conclusions can be drawn at this point as to how results from [...] laboratory trials might translate in the field".[1946] This statement, in our view, implies that this study *per se* cannot be said to evaluate the alleged risks identified by Austria in its Reasons document. In addition, given the lack of conclusions concerning how the laboratory trials might translate in the field noted above, we do not consider that the second Hilbeck study provides an evaluation of the potential for adverse effects on insect health from the presence of Bt toxin in food or feedstuffs. Therefore, we do not consider that this study in itself constitutes a risk assessment within the meaning of either the first or the second clause of Annex A(4) and Article 5.1, although we accept that it may be of relevance for a risk assessment.

7.3100 Finally, we recall that the European Communities provided as evidence a study by Austria on toxicological and allergological risks related to biotech products (the March 2003 document).[1947] As we noted above with respect to T25 maize, we consider that this study evaluates risk assessment *procedures*, and not the potential for adverse effects on human or animal health arising from the consumption of specific foods containing or consisting of GMOs. We therefore think that this March 2003 study does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3101 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Austria to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3102 Furthermore, in connection with the documents relied on by Austria, we should also note the European Communities' argument that Austria's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Austrian safeguard measure include the fact that, from Austria's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3103 We have found above that none of the documents relied on by Austria with regard to its safeguard measure on MON810 maize constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by Austria which constitutes a risk assessment for MON810 maize. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1948] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[1949] In

[1945] Exhibit EC-158/At. 27.
[1946] Exhibit EC-158/At. 27 p. 485.
[1947] *See supra*, para. 7.3069.
[1948] EC reply to Panel question No. 107.
[1949] Exhibits EC-159/Ats. 1-2; CDA-82; US-55 (referencing original SCP risk assessment); ARG–44 (referencing original SCP risk assessment).

any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1

7.3104 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the Austrian safeguard measure on MON810 maize is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3105 We now turn to the question of whether, at the time of establishment of this Panel, the Austrian safeguard measure on MON810 maize was "based on" either the risk assessment of the lead CA or that conducted by the SCP.[1950]

7.3106 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Austria's safeguard measure on MON810 maize and the risk assessments performed by the lead CA and the SCP in relation to MON810 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to MON810 maize;

(b) the European Communities or Austria did not explain, by reference to these risk assessments, how and why Austria assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Austria's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Austria's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that MON810 maize is likely to cause adverse effects on human or animal health and the environment.

7.3107 Thus, in view of our conclusion that Austria's safeguard measure on MON810 maize cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to MON810 maize, and recalling the fact that no other risk assessment which might reasonably

[1950] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP.

support Austria's safeguard measure has been provided to us, we find that the Austrian safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1951]

Overall conclusions

7.3108 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment.

7.3109 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether the Austrian safeguard measure on MON810 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Austrian safeguard measure on MON810 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(v) France – MS1/RF1 oilseed rape (EC-161)*

7.3110 We now turn to the analysis of France's measure on MS1/RF1 oilseed rape (EC-161). The first issue we will address is whether the documents France relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3111 We recall from the Reasons document that the main concerns of France were related to the risk of contamination of traditional oilseed rape by genetically modified oilseed rape; the likelihood of transfer of the herbicide-tolerance gene to adventitious flora; and the overall impact on the environment or long-term ecological effects of MS1/RF1 oilseed rape (EC-161).[1952] With respect to France's concerns related to gene flow and pollen dispersal, we note that France makes reference to a number of scientific studies. However, these studies were not submitted as evidence to the Panel. We therefore cannot determine whether any of these studies constitutes a risk assessment on which the safeguard measure on MS1/RF1 oilseed rape (EC-161) is based.

[1951] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[1952] Exhibits EC-161/At. 2 and EC-162/At. 5.

7.3112 We further recall that the decision by France to extend the suspension of the authorization for placing on the market of MS1/RF1 oilseed rape (EC-161) in July 2001 and July 2003 were allegedly based on the conclusions of opinions delivered by the BEC in 2001 and 2003, respectively. We note that the BEC delivered a further opinion on MS1/RF1 oilseed rape (EC-161) on 13 February 2004.[1953] We recall that we must assess whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was based on a risk assessment as of August 2003, when this Panel was established. Since the 2004 opinion of the BEC was delivered after the time of establishment of the Panel, we do not take it into account as part of our analysis.

7.3113 Having identified the documents which France relies on to justify its safeguard measure, we can now go on to determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*. We recall our previous conclusion that France's concerns fall within the scope of Annex A(1)(a) and/or (d). We consider, therefore, that the first clause of Annex A(4) to the *SPS Agreement* provides the relevant definition for the "risk assessment" to be carried out for France's measure on MS1/RF1 oilseed rape (EC-161) and consider that the requirements for such a risk assessment, as clarified by the Appellate Body in *Australia–Salmon*, apply.

7.3114 The Panel begins its analysis with France's Reasons document. In this document, France points to new scientific evidence which, according to France, raises uncertainty with respect to the potential risks related to MS1/RF1 oilseed rape (EC-161), in particular regarding the environmental effects associated with out-crossing between MS1/RF1 oilseed rape (EC-161) and other plants. According to France, this new scientific evidence raises doubts with regard to the environmental safety of MS1/RF1 oilseed rape (EC-161).

7.3115 We note that nothing in the Reasons document indicates that France has made a new assessment of the alleged risks in the light of the scientific evidence invoked by France. Indeed, we are of the view that the statement in the Reasons document that "these possible developments in agronomic practices must be assessed in terms of their overall impact on the environment"[1954] implies that France is calling for further study rather than presenting a new assessment. Furthermore, the Reasons document notes that a prohibition of MS1/RF1 oilseed rape (EC-161) is justified "pending a clear and full scientific report on these issues".[1955] Consequently, we are of the view that the Reasons document does not itself constitute an "assessment" of risks within the meaning of Annex A(4) and Article 5.1.[1956]

7.3116 We also note that while the Reasons document refers to the likelihood of risks arising in respect of MS1/RF1 oilseed rape (EC-161), the document does not "evaluate" the likelihood of the risk of establishment, entry or spread of a pest (*in casu*, hybrid plants) "according to the [SPS] measures which might be applied". It is merely concluded that "dispersal into the environment [of herbicide tolerance transgenes] is likely".[1957] The discussion in the Reasons document cannot therefore be said to meet the definition of a risk assessment as defined in Annex A(4).

[1953] Exhibit EC-161/At. 10.
[1954] Exhibit EC-161/At. 2 p. 3.
[1955] *Ibid.*, p. 4.
[1956] We note that in its Reasons document, France refers to numerous scientific studies. However, these studies were not submitted to the Panel as evidence. Therefore, we can not evaluate in detail whether any of these documents would constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.
[1957] Exhibit EC-161/At. 2, p. 2.

7.3117 Turning to the BEC opinions, we recall that the BEC apparently issued an opinion in 2001 which allegedly supported France's decision to prolong the safeguard measure for a further two years. As we noted earlier, it is not clear to the Panel whether this opinion of the BEC was submitted to us as evidence. An undated report by the BEC has been provided.[1958] This document makes reference to the French decision to take a safeguard measure in November 1998, and to production data in 2000. The document addresses concerns with regard to both genetically modified sugar beet and oilseed rape. For the sake of our analysis, we will assume that this document is the 2001 opinion of the BEC (hereafter "the 2001 BEC report"). According to this report, the BEC "proceeded to make an expert appraisal of the scientific information which was available for assessing the impacts on the environment of genetically modified oilseed rape and beet plants which were tolerant to a herbicide".[1959] In this context, reference is made to documents appended to the opinion, however these documents were not provided to the Panel. The 2001 BEC report identifies some possible ecological and agronomic impacts of herbicide tolerant oilseed rape. These include the "possible proliferation of the tolerant plants in the ecosystem"; the "possible development of adventitious flora [...]"; and possible changes in the ability of farmers to carry out weed control.[1960]

7.3118 We note that the 2001 BEC report purports to provide some evaluation of likelihood with respect to the "ability of oilseed rape to hybridize".[1961] Specifically, the report indicates that "the hybridizations which have been observed in England and in certain countries in the north of Europe are very unlikely in France".[1962] The report indicates that the studies in France focussed on "the analysis of the probability" of obtaining three types of hybrids, involving wild radish (*Raphanus raphanistrum*), short-pod mustard (*Hirschfeldia incana*) and wild mustard (*Sinapis arvensis*). The report indicates that "oilseed rape hybridizes rarely with wild radish, even more rarely with short-pod mustard and not at all with wild mustard".[1963] With respect to consequences for the environment, the report states: "In the case of genes for tolerance to a herbicide, and in natural environments, there is no information which leads one to suppose that the ability of plants, which have received these genes, to multiply and invade environments should be different from that of any other oilseed rape plant which has escaped from farmed land or from that of any other wild-type crucifer."[1964]

7.3119 The 2001 BEC report goes on to identify a number of areas for further study.[1965] Finally, the report contains the following "general conclusion": "The Biomolecular Engineering Committee is of the opinion that, even if cultivating genetically modified oilseed rapes which are tolerant to herbicides does not present any direct risks for the environment, a transitional phase of two years would make it possible, by carrying out experiments on areas of different scale, to validate the forms of management which are proposed for weed control and for coexistence between two methods of agriculture."[1966]

7.3120 With reference to the requirements for a risk assessment as clarified by the Appellate Body in *Australia–Salmon*[1967], the Panel notes that unlike the Reasons document, the 2001 BEC report does appear to provide some evaluation of the likelihood of entry, establishment or spread of one of the "pests" of concern, that is of hybrids between herbicide tolerant oilseed rape and some wild plants.

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[1958] Exhibit EC-161/At. 6, with translations of the summary and body of this document apparently submitted as EC-161/Ats. 7 and 8, respectively. None of these submissions are dated.
[1959] Exhibit EC-161/At. 8, p.5.
[1960] *Ibid*., p.5.
[1961] *Ibid*., p.9
[1962] *Ibid*.
[1963] *Ibid*.
[1964] *Ibid*., p. 10.
[1965] *Ibid*., p. 11.
[1966] Exhibit EC-161/At. 8, p. 19.
[1967] *See supra*, para. 7.3040.

However, this is addressed, in the context of the BEC report, with respect to all herbicide tolerant oilseed rape varieties and not specifically those which are genetically modified. Furthermore, we note that the 2001 BEC report does not provide any analysis of the associated potential biological and economic consequences of these hybrids, nor does it purport to evaluate the likelihood of entry, establishment or spread of these hybrids according to the SPS measures which might be applied. Consequently, we do not consider that the 2001 BEC report fulfils all of the criteria of a risk assessment in accordance with the definition in Annex A(4).

7.3121 The decision by France in July 2003 to further prolong its safeguard measure on MS1/RF1 oilseed rape (EC-161) was allegedly supported by another opinion of the BEC issued in July 2003 (hereafter "the 2003 BEC report").[1968] We note that the 2003 BEC report refers to the concerns identified by France at the time the safeguard measure was first taken. The 2003 BEC report points to some new elements of information and to on-going research which it indicates may shed new light on some of the conclusions of the 2001 BEC report.[1969] However, the 2003 BEC report does not contain any evaluation of new information. Rather, the report calls for further analysis and for the organization of a scientific workshop to consider whether this information might affect the opinions contained in the 2001 BEC report.[1970] We note that this workshop, which was held in November 2003, resulted in the issuance of another report by the BEC in February 2004. As we have previously indicated, we will not take into account the BEC opinion of February 2004.[1971]

7.3122 In the light of the foregoing, we conclude that the above-mentioned documents relied on by France to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3123 Furthermore, in connection with the documents relied on by France, we should also note the European Communities' argument that France's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the French safeguard measure include the fact that, from France's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3124 We have found above that none of the documents relied on by France with regard to its safeguard measure on MS1/RF1 oilseed rape (EC-161) constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by France which constitutes a risk assessment for MS1/RF1 oilseed rape (EC-161). The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1972] As we understand it, the European Communities in this instance is referring to the risk assessment conducted by the lead CA. This is because the Commission did not consult the SCP before approving MS1/RF1 oilseed rape (EC-161).[1973] As we have noted above, it is not in dispute that the lead CA's assessment constitutes a risk assessment within the meaning of Annex A(4) and Article 5.1.

[1968] Exhibit EC-161/At. 9.
[1969] Exhibit EC-161/At. 9 p. 1.
[1970] Exhibit EC-161/At. 9 p. 3.
[1971] *See supra*, para. 7.3112.
[1972] EC reply to Panel question No. 107.
[1973] The SCP was only established in 1997. Exhibits US-61; CDA-69.

7.3125 In addition, we recall that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessment conducted by the lead CA was no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is "based on" this risk assessment, we do not need to examine this issue further.

"Based on"

7.3126 We now turn to the question of whether, at the time of establishment of this Panel, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was "based on" the risk assessment of the lead CA.

7.3127 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to France's safeguard measure on MS1/RF1 oilseed rape (EC-161) and the risk assessment performed by the lead CA in relation to T25 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to MS1/RF1 oilseed rape (EC-161);

(b) the European Communities or France did not explain, by reference to these risk assessments, how and why France assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, France's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between France's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that MS1/RF1 oilseed rape (EC-161) is likely to cause any adverse effects on human health and the environment.

7.3128 Thus, in view of our conclusion that France's safeguard measure on MS1/RF1 oilseed rape (EC-161) cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to MS1/RF1 oilseed rape (EC-161), and recalling the fact that no other risk assessment which might reasonably support France's safeguard measure has been provided to us, we find that the French safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1974]

[1974] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

Overall conclusions

7.3129 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment.

7.3130 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS292 (Canada), it is necessary to examine, in addition, whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the French safeguard measure on MS1/RF1 oilseed rape (EC-161) with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(vi) France – Topas oilseed rape*

7.3131 We now turn to the analysis of France's measure on Topas oilseed rape. The first issue we will address is whether the documents France relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3132 We note that France relied on the same documents with respect to its safeguard measure on Topas oilseed rape as for its measure on MS1/RF1 oilseed rape (EC-161). We recall our analysis of the relevant documents relied on by France in respect of its safeguard measure on MS1/RF1 oilseed rape (EC-161) above. Based on a review of these documents, we found that none constituted a risk assessment within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. Consistent with our analysis above, we also find in the case of the French safeguard measure on Topas oilseed rape that none of the documents relied on by France constitute a risk assessment.

7.3133 Furthermore, in connection with the documents relied on by France, we should also note the European Communities' argument that France's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the French safeguard measure include the fact that, from France's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3134 We have found above that none of the documents relied on by France with regard to its safeguard measure on Topas oilseed rape constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by France which constitutes a risk assessment for Topas oilseed rape. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1975] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[1976] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3135 In addition, we recall that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the French safeguard measure on Topas oilseed rape is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3136 We now turn to the question of whether, at the time of establishment of this Panel, the French safeguard measure on Topas oilseed rape was "based on" either the risk assessment of the lead CA or that conducted by the SCP.[1977]

7.3137 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply *mutatis mutandis*, to France's safeguard measure on Topas oilseed rape and the risk assessments performed by the lead CA and the SCP in relation to Topas oilseed rape. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to Topas oilseed rape;

(b) the European Communities or France did not explain, by reference to these risk assessments, how and why France assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, France's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between France's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Topas

[1975] EC reply to Panel question No. 107.
[1976] Exhibits EC-162/At. 1; CDA-63; US-62 (referencing original SCP risk assessment).
[1977] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP.

oilseed rape is likely to cause adverse effects on human or animal health and the environment.

7.3138 Thus, in view of our conclusion that France's safeguard measure on Topas oilseed rape cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to Topas oilseed rape, and recalling the fact that no other risk assessment which might reasonably support France's safeguard measure has been provided to us, we find that the French safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1978]

Overall conclusions

7.3139 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment.

7.3140 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS292 (Canada), it is necessary to examine, in addition, whether the French safeguard measure on Topas oilseed rape is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the French safeguard measure on Topas oilseed rape with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(vii) Germany – Bt-176 maize*

7.3141 We now turn to Germany's safeguard measure on Bt-176 maize. We recall that we must determine whether Germany's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the documents Germany relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3142 We recall that Germany (Robert Koch Institute) notified its decision to prohibit Bt-176 maize to the Commission in a letter dated 4 April 2000.[1979] In this letter, Germany explained the reasons for

[1978] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[1979] Exhibit EC-158/At. 21. We note that the concerns of Germany were also set out in an earlier letter addressed by the Robert Koch Institute to the Commission on 2 March 2000 (Exhibit EC-158/At. 19_trans), as

adopting its safeguard measure on Bt-176 maize. The letter refers to the following scientific studies in support of Germany's safeguard measure:

(i) Study by Losey (1999), "Transgenic pollen harms monarch larvae"[1980];
(ii) Study by Hilbeck *et al.* (January 1999), "Prey-mediated effects of Cry1Ab toxin and protoxin and Cry2A protoxin on the predator *Chrysoperla carnea*"[1981];
(iii) Study by Hilbeck *et al.* (1998), "Toxicity of *Bacillus thuringiensis* Cry1Ab Toxin to the Predator *Chrysoperla carnea* (Neuroptera: Chrysopidae)"[1982];
(iv) Study by Hilbeck *et al.* (1998), "Effects of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae)"[1983];
(v) Study by Saxena *et al.* (1999), "Insecticidal toxin in root exudates from *Bt* corn"[1984];
(vi) Öko-Institut e. V. (Dec. 1999) – Study on the "Therapeutical relevance of antibiotics in connection with the use of antibiotic resistance genes in transgenic plants"[1985].

7.3143 Having determined the documents relied on by Germany with respect to its safeguard measure on Bt-176 maize, we must now determine whether one or more of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

7.3144 We recall our conclusions that the concerns identified by Germany, relating to possible effects on non-target organisms, the development of resistance to Bt toxins in insects, the possible adverse effects of Bt toxin in the soil and potential for development of antibiotic resistance, fall within the scope of Annex A(1)(a), (b) and/or (d) of the *SPS Agreement*. Both clauses of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for SPS measures which have these types of purposes. As discussed earlier, Germany's concern relating to potential increased development of antibiotic resistance could also fall within the scope of Annex A(1)(b) of the *SPS Agreement*. The second clause of Annex A(4) to the *SPS Agreement* defines the "risk assessment" to be carried out for SPS measures which fall within the scope of Annex A(1)(b).

7.3145 We begin our analysis with Germany's Reasons document. That document includes references to possibilities of risks, but does not evaluate the potential or likelihood of such risks occurring. For example, the document states that "it cannot be excluded that unacceptable adverse effects on other lepidoptera species and on some other insects would occur."[1986] Similarly, the document states that "an ecologically unacceptable development of resistance may occur in the event of unrestricted cultivation"[1987] of Bt maize. With regard to possible effects of Bt-toxin on soil micro-organisms, the Reasons document states that these effects "cannot be excluded".[1988] Finally, the Reasons document notes that increased development of antibiotic resistance following uptake of the antibiotic resistance gene contained in Bt-176 maize "cannot [be] excluded".[1989] As noted by us

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well as in a letter from the Robert Koch Institute to Gaedertz Attorneys-at-Law on 31 March 2000 (Exhibit US-65).

[1980] Exhibit EC-158/At. 24.
[1981] Exhibit EC-158/At. 25.
[1982] Exhibit EC-158/At. 26.
[1983] Exhibit EC-158/At. 27.
[1984] Exhibit EC-158/At. 28.
[1985] Exhibit EC-158/At. 29.
[1986] Exhibit EC-158/At. 21, p.1.
[1987] *Ibid*., p. 2.
[1988] *Ibid*.
[1989] *Ibid*.

above, the Appellate Body in *Australia – Salmon* clarified that a risk assessment as defined in the first clause of Annex A(4) must evaluate the likelihood or probability of relevant risks.[1990]

7.3146 Regarding the concern over the possible development of antibiotic resistance, we further note the statement in the Reasons document to the effect that on the basis of current knowledge, unacceptable adverse effects are not to be expected in view of the already widespread resistance in bacteria to the relevant antibiotics, if, as the EC approval decision envisages, the quantity of Bt-176 maize seeds which may be sown is limited to 12 tonnes/year.[1991] Thus, the Reasons document suggests that there is only a small potential for adverse effects on human or animal health arising from the presence of ARMG in Bt-176 maize. However, the Reasons document does not itself contain and provide the information necessary to an evaluation of the potential for adverse effects on human or animal health. Accordingly, we consider that the Reasons document constitutes, not a complete, self-contained, scientific evaluation of the potential for adverse effects, but only part of such an evaluation. Hence, we are of the view that the Reasons document on its own does not meet the definition of a risk assessment as provided in the second clause of Annex A(4).

7.3147 We now turn to the scientific studies which Germany relied on in respect of its safeguard measure. The first four of these studies relate to impacts of Bt toxins on insects while the fifth examines the use of antibiotic resistance marker genes in transgenic plants. We recall that we have previously examined the Losey study as well as the two 1998 Hilbeck *et al*. studies in the context of our consideration of Austria's safeguard measure on MON810 maize. We recall our conclusions that none of these studies evaluate the potential or likelihood of the occurrence of the adverse effect identified in Germany's Reasons document. We do not consider, therefore, that any of these three studies in themselves constitute a risk assessment, although we accept that they may be of relevance for an eventual risk assessment.

7.3148 The 1999 Hilbeck *et al.* document describes laboratory feeding experiments which were carried out to study the effects of insects feeding on other insects which had had an artificial diet containing Bt proteins. While the study's conclusions highlight the importance of assessing the non-target impacts of Bt toxins, it does not do this in the context of the Bt-176 maize. In particular, this study does not provide an evaluation of the likelihood of risks associated with the insects eating Bt-176 maize plants. Nor does it evaluate the likelihood of an outcome in the field. For example, the study notes "field studies must be conducted to assess the ecological consequences"[1992] of the study's results. We do not consider, therefore, that this study in and of itself constitutes a risk assessment, although we accept that it may be of relevance for an eventual risk assessment.

7.3149 The fifth study, by Saxena *et al.*, examines the potential for Bt toxin to be released into the soil from the roots of Bt maize. The study used a variety of Bt maize called NK4640Bt which differs from the variety which is subject to the German safeguard measure. While the study measured the toxin released into the soil surrounding the roots of maize plants, the authors note that they have "no indication of how soil communities might be affected by Bt toxin in [...] the field" and that "[f]urther investigations will be necessary to shed light on what might happen underground".[1993] Thus, this study neither purports to evaluate the potential consequences associated with the release of Bt exudates into the soil, nor provides information specifically related to the product at issue in this safeguard measure, Bt-176 maize. Therefore, we do not consider that this study, by itself, meets the definition of a risk assessment as provided in Annex A(4).

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[1990] Appellate Body Report, *Australia – Salmon*, paras. 123-124.
[1991] Exhibit EC-158/At. 21, p. 3.
[1992] Exhibit EC-158/At. 25 p. 11.
[1993] Exhibit EC-158/At. 28, p. 480.

7.3150 The final study, by the Öko-Institut e.V., provides an overview of the types of antibiotics which could be affected by the possible development of resistance to antibiotics due to the use of antibiotic resistance marker genes in transgenic plants. The study describes the therapeutic importance of a variety of antibiotics, but does not evaluate the likelihood that the consumption of transgenic plants in general, much less of Bt-176 maize specifically, will lead to the spread of diseases due to the development of resistance to the relevant antibiotics. The authors state that "the wide dispersal of [antibiotic resistance] genes via agriculture, animal feeding and in the human food chain provides an additional path for the development of antibiotic resistance" and that "this risk is not negligible" as outside hospitals the resistance problem was still smaller.[1994] The study further states that "particularly worrying" is the fact that "there are indications" that the transfer rate of antibiotic resistance in soils can be furthered by herbicide use.[1995] The study goes on to say that because herbicide applications are the rule in agriculture and because many ARMG in transgenic plants were transferred together with herbicide resistance genes, this "possibly creates conditions which could [...] have a promoting influence on the development of resistance".[1996] The study therefore recommends that ARMG should not be used any more.

7.3151 Hence, the study by the Öko-Institut asserts that there is a potential for adverse effects on human or animal health from the presence of ARMG in transgenic plants used as or in food/feed. However, it does not "evaluate" that potential. Indeed, the study devotes only a few paragraphs to transgenic plants containing ARMG as an additional source of possible development of antibiotic resistance. Moreover, the study does not evaluate the likelihood of spread of diseases due to the presence of ARMG in transgenic plants. As indicated, the study refers to possibilities, but it does not determine likelihoods. We therefore do not consider that this study meets the definition of a risk assessment as provided in Annex A(4).

7.3152 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Germany to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3153 Furthermore, in connection with the documents relied on by Germany, we should also note the European Communities' argument that Germany's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the German safeguard measure include the fact that, from Germany's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031 and 7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3154 We have found above that the documents provided by the Parties in relation to Germany's safeguard measure on Bt-176 maize on which Germany relied on do not constitute a risk assessment. However, the European Communities contends that there is a document other than the documents relied on by Germany which constitutes a risk assessment for Bt-176 maize. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1997] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to any of the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE),

[1994] Exhibit EC-158/At. 29, p. 28.
[1995] *Ibid*.
[1996] *Ibid*.
[1997] EC reply to Panel question No. 107.

the Scientific Committee for Animal Nutrition (SCAN) or the SCF.[1998] In any event, we have noted above that it is not in dispute that these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3155 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Germany's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3156 We now turn to the question of whether, at the time of establishment of this Panel, the German safeguard measure on Bt-176 maize was "based on" either the risk assessment of the lead CA or any of those conducted by the SCPE, the SCAN or the SCF.[1999]

7.3157 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Germany's safeguard measure on Bt-176 maize and the risk assessment performed by the lead CA and the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal Nutrition (SCAN) or the SCF in relation to Bt-176 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and those which were conducted by the SCPE, the SCAN or the SCF with regard to Bt-176 maize;

(b) the European Communities or Germany did not explain, by reference to these risk assessments, how and why Germany assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Germany's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Germany's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Bt-176 maize will give rise to any adverse effects on human or animal health and the environment.

[1998] Exhibit EC-158/Ats. 1-3; EC-158/At. 4; EC-158/At. 5; EC-158/At. 6.

[1999] We recall that we must examine as part of our analysis whether the safeguard measure is based on any of those risk assessments, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or those conducted by the SCPE, the SCAN or the SCF.

7.3158 Thus, in view of our conclusion that Germany's safeguard measure on Bt-176 maize cannot be considered to be "based on" the risk assessment performed by the lead CA or the risk assessments which were conducted by the SCPE, the SCAN or the SCF in relation to Bt-176 maize, and recalling the fact that no other risk assessment which might reasonably support Germany's safeguard measure has been provided to us, we find that the German safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2000]

Overall conclusions

7.3159 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment.

7.3160 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether the German safeguard measure on Bt-176 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the German safeguard measure on Bt-176 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(viii) Greece – Topas oilseed rape*

7.3161 We now turn to the Greek safeguard measure on Topas oilseed rape. We recall that we must determine whether Greece's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the documents Greece relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3162 We start by recalling the documents on record in respect of this safeguard measure. We recall that Greece notified its Ministerial Decision to prohibit Topas oilseed rape to the Commission in a document dated 3 November 1998 (hereafter the "Reasons document"). In this document, Greece explained the reasons for adopting its safeguard measure on Topas oilseed rape. [2001]

[2000] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the German safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[2001] Exhibit EC-162/At. 4

7.3163 Furthermore, in a letter of 3 March 2004 to the Commission, Greece provides further justification for its safeguard measure on Topas oilseed rape.[2002] In relation to this letter, we recall that our task is to assess whether the Greek safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that the Greek safeguard measure was not based on a risk assessment in August 2003. We note that the March 2004 letter makes reference to two scientific studies. The first study was not submitted to the Panel. It is from the European Environment Agency and is entitled "Genetically Modified Organisms: The significance of gene flow through pollen transfer" and dated 21 March 2002. According to the March 2004 letter, the study characterizes oilseed rape as a high risk crop as far as gene transfer between crops and wild relative species is concerned. The second study is from the UK Advisory Committee on Releases to the Environment (ACRE) and is dated January 2004.[2003] According to the letter, the study concerns spring oilseed rape and confirms the March 2002 study. The ACRE study apparently refers to adverse effects on biodiversity, a significant decrease of the wild weed population and harmful effects on the higher levels of the food chain of the crop in question as compared to conventional crops. Considering that the first study was not submitted to us and that the second study dates from after August 2003, we do not review these studies with a view to determining whether they constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3164 Finally, we note that in a letter of 17 March 2004 to the Commission, Greece refers to additional documents in support of its safeguard measure on Topas oilseed rape.[2004] The following documents were submitted to us and will be taken into account:

(i) Study by the Office of the Gene Technology Regulator (July 2002), "The biology and ecology of canola (Brassica napus)"[2005];
(ii) Several studies that constitute part of the Farm Scale Evaluations of spring-sown genetically modified crops (October 2003)[2006];
(iii) Study by Wilkinson *et al.* (2003), "Hybridization Between *Brassica napus* and *B. rapa* on a National Scale in the United Kingdom"[2007].

7.3165 Having determined the documents relied on by Greece with respect to its safeguard measure on Topas oilseed rape, we must now determine whether any of these documents constitutes a "risk assessment" within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.

7.3166 As with Austria's safeguard measure for T25 maize, given the concerns raised by Greece in the context of Topas oilseed rape relating to environmental risks and consumer health, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for Greece's measure on Topas oilseed rape.

7.3167 We start our examination with the Reasons document notified by Greece in respect of its safeguard measure on Topas oilseed rape. The Reasons document alleges risks for the natural environment of Greece from spillage of seeds of Topas oilseed rape during transport. Specifically, the

[2002] Exhibit EC-162/At. 6_transl.
[2003] Exhibit EC-40.
[2004] Exhibit EC-162/At. 7.
[2005] Exhibit EC-162/At. 13.
[2006] Exhibit EC-162/At. 9-11. Although the Farm Scale Evaluations were published in October 2003, they contain the results of evaluations conducted over the 3-year period from 2000-2002.
[2007] Exhibit EC-162/At. 12.

Reasons document asserts that "it is certain that the seeds will escape into the environment and will give viable plants".[2008] It also asserts that "it is certain that [...] there will arise hybrid plants [weeds] bearing the glufosinate tolerance gene".[2009] It further asserts that glufosinate tolerant weeds "will" have a selective advantage over other weeds and consequently "will" dominate.[2010] Also, "there exists the risk" that, following the release of other herbicide tolerant GM plants, multiresistant weeds will arise.[2011] Finally, the resistant weeds "will" spread not only in the agricultural environment but also in the natural environment.[2012] As noted above, the Appellate Body in *Australia – Salmon* clarified that a risk assessment must evaluate the likelihood or probability of particular risks.[2013] The Reasons document reaches conclusions regarding the likelihood of the spread of certain pests, but it reaches these conclusions without any prior "evaluation" of relevant data and information. The relevant passages in the Reasons document are only a few paragraphs long and no results from studies or tests are contained in, or annexed to, the document. Additionally, we note that the Reasons document does not evaluate the likelihood of the spread of pests according to the SPS measures which might be applied. The document only addresses the likelihood of risks in the situation where no SPS measure is applied, *i.e.*, where Topas oilseed rape is released into the environment. For these reasons, we are of the view that the discussion in the Reasons document of potential environmental risks does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3168 The Reasons document further notes that some of the wild plant varieties at issue are collected and consumed in Greece as food. Greece points out in this regard that if out-crossing were to confer on these wild plant varieties the herbicide resistance trait, the consequences of the consumption of these varieties would be unpredictable. Greece observes that these consequences have not been considered in the original risk assessment prior to the approval of Topas oilseed rape. Thus, while the Reasons document refers to unspecified adverse effects on human health arising from the consumption of hybrid plants, it does not provide any evaluation of the potential for such adverse effects to occur. We therefore do not consider that the discussion in the Reasons document of potential risks for the health of consumers constitutes a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3169 We now turn to the scientific studies relied on by Greece in respect of its safeguard measure. The first study, by the Office of the Gene Technology Regulator, focuses on the biology and ecology of a particular variety of oilseed rape – canola, or *Brassica napus* – and highlights the potential for outcrossing between this type of plant and its weedy relatives. The study states that while "the probability of outcrossing appears to be low", the biology of canola "ensures that a substantial number of outcrossed seeds can still be produced".[2014] Thus, the study evaluates the likelihood of outcrossing from canola. However, it does not do so for Topas oilseed rape, but for canola in general, including for canola which is not genetically modified. Also, consistent with its stated objective of addressing the biology and ecology of canola, the study does not evaluate the likelihood of the entry, establishment or spread of undesired cross-breeds according to the SPS measures which might be applied. We therefore do not consider that this study meets the definition of a risk assessment as provided in Annex A(4).

[2008] Exhibit EC-162/At. 4.
[2009] *Ibid*.
[2010] *Ibid*.
[2011] *Ibid*.
[2012] *Ibid*.
[2013] Appellate Body Report, *Australia – Salmon*, paras. 123-124.
[2014] Exhibit EC-162/At. 13 p. 13.

7.3170 The second set of studies report results from the Farm Scale Evaluations (FSEs) conducted in the United Kingdom. The first of these studies, by Squire *et al.*, summarizes the methods and results of the FSEs. This study emphasizes the difficulty of predicting the impact of growing GM crop varieties which are tolerant to herbicides (hereafter "GMHT crops"), due to the uncertainty about farmer management decisions. The study notes that "predictions [...] are particularly difficult since what happens will be strongly affected by the preference of farmers and by current economics."[2015] Another FSE study, by Haughton *et al.*, reports results regarding the impacts of the management of GMHT varieties on arthropods with particular reference to the weed vegetation that supports them. The study summarizes the effects on arthropods across a variety of GMHT crops, and notes that "the effects were indirect and related to herbicide management".[2016] The third study referenced by Greece, by Hawes *et al.*, seeks to determine whether differences in weed populations and biomass due to the impact of GMHT cropping result in changes in population trends of particular insects. The study's conclusions notes that "commercialization of GMHT crops would [...] be likely to have a range of effects on plant and invertebrate functional groups in the long-term".[2017] Each of these studies discusses GMHT crops in general rather than focusing specifically on the Topas oilseed rape, and none of these studies evaluates the likelihood of adverse effects from the entry, establishment or spread of GMHT crops according to the SPS measures which might be taken by Greece to reduce any potential risks. We therefore do not consider that these studies meets the definition of a risk assessment as provided in Annex A(4).

7.3171 The Wilkinson *et al.* study reports results regarding hybridization between two varieties of oilseed rape, *Brassica napus* and *B. rapa.*[2018] The study provides an estimate of GM hybrid abundance for the United Kingdom and notes that its findings help "set targets for strategies to eliminate hybridization and represent the first step toward quantitative risk assessment on a national scale."[2019] It also states that the presence of GM hybrids is not a risk in itself and does not imply inevitable ecological change. It notes that hybrid fitness and other factors affecting the likelihood of ecological change should also be assessed.[2020] These statements serve to demonstrate that the study does not take into account all factors that are relevant to an evaluation of the likelihood of environmental change caused by gene flow. Accordingly, we consider that the study does not constitute a risk assessment as defined in Annex A(4) and required by Article 5.1. We also note that the study does not claim that the estimates it provides are valid outside mainland Britain. We therefore do not consider that this study meets the definition of a risk assessment as provided in Annex A(4).

7.3172 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Greece to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3173 Furthermore, in connection with the documents relied on by Greece, we should also note the European Communities' argument that Greece's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Greek safeguard measure include the fact that, from Greece's perspective, relevant scientific evidence was or is insufficient. We recall our previous

[2015] Exhibit EC-162/At. 9 p. 1795.
[2016] Exhibit EC-162/At. 10 p. 1875.
[2017] Exhibit EC-162/At. 11 p. 1912.
[2018] We understand from the application for the deliberate release of this product that *Brassica napus* is the species of oilseed rape which has been modified to produce Topas oilseed rape.
[2019] Exhibit EC-162/At. 12, p. 457.
[2020] *Ibid*., p. 459.

consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3174 We have found above that the documents provided by the Parties in relation to Greece's safeguard measure on Topas oilseed rape on which Greece relied do not constitute a risk assessment. However, the European Communities contends that there is a document other than the documents relied on by Greece which constitutes a risk assessment for Topas oilseed rape. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[2021] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[2022] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1

7.3175 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Greece's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3176 We now turn to the question of whether, at the time of establishment of this Panel, the Greek safeguard measure on Topas oilseed rape was "based on" either the risk assessment of the lead CA or that conducted by the SCP.[2023]

7.3177 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Greece's safeguard measure on Topas oilseed rape and the risk assessments performed by the lead CA and the SCP in relation to Topas oilseed rape. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to Topas oilseed rape;

(b) the European Communities or Greece did not explain, by reference to these risk assessments, how and why Greece assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such

[2021] EC reply to Panel question No. 107.
[2022] Exhibits EC-162/At. 1; CDA-63; US-70 (referencing original SCP risk assessment).
[2023] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP.

uncertainties or constraints, Greece's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Greece's safeguard measure, which imposes a prohibition, and risk assessments which we understand found no evidence that Topas oilseed rape will give rise to any adverse effects on human or animal health and the environment.

7.3178 Thus, in view of our conclusion that Greece's safeguard measure on Topas oilseed rape cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to Topas oilseed rape, and recalling the fact that no other risk assessment which might reasonably support Greece's safeguard measure has been provided to us, we find that the Greek safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2024]

Overall conclusions

7.3179 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment.

7.3180 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS292 (Canada), it is necessary to examine, in addition, whether the Greek safeguard measure on Topas oilseed rape is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Greek safeguard measure on Topas oilseed rape with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(ix) Italy – T25 maize, MON810 maize, MON809 maize, Bt-11 maize (EC-163)*

7.3181 We now turn to the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We recall that we must determine whether Italy's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the documents Italy relies on to justify its safeguard measure meet the definition of a risk assessment.

[2024] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Greek safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

"Risk assessment"

7.3182 We start by summarizing the documents on record in respect of this safeguard measure. We recall that Italy issued a decree on 4 August 2000 suspending the trade and use of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163).[2025] As stated in the Decree, the decision by Italy to apply a safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) was based on opinions issued by the Italian Superior Council of Health and Superior Institute of Health. We recall that only the 28 July 2000 opinion of the Superior Institute of Health referred to in the Italian Decree was provided to the Panel.[2026] The relevant conclusions of the opinion of the Superior Institute of Health set out in the Decree were summarized above.

7.3183 Having determined the documents relied on by Italy with respect to its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), we must now determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

7.3184 We recall that the concerns identified by Italy relate to the protection of human health from potential risks associated with the consumption of the relevant GM maize products as well as potential risks arising from the "environmental release" of the relevant GMOs or their products. Regarding the latter category of risks, we consider that the first clause of Annex A(4) to the *SPS Agreement* provides the applicable definition for the "risk assessment" to be carried out for Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). Regarding the former category of risks – risks associated with the consumption of the relevant GM maize products – we consider that the second clause of Annex A(4) to the *SPS Agreement* provides the applicable definition. We note that, unlike for the definition of risk assessment contained in the first clause of Annex A(4), WTO jurisprudence provides little guidance on the meaning of key concepts contained in the definition provided in the second clause. The Appellate Body merely observed in this respect that the first clause is substantially different from the second clause, and that the second clause requires "only" the evaluation of the "potential" for adverse effects on human or animal health arising from the presence of certain substances in foods, whereas the first clause requires an evaluation of the "likelihood" of entry, establishment or spread of a pest or disease and of the associated biological and economic consequences.[2027] We note that the dictionary defines the term "potential" as "the possibility of something happening [...] in the future".[2028]

7.3185 We start with the Decree notified by Italy in respect of its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). This Decree makes reference to "an exposé by an environmentalist association regarding to the simplified authorization procedure for the placing on the market"[2029] of these four maize products, and assertions by the environmentalist association that the condition of "substantial equivalence" required for the use of the simplified procedure was not met for these products. The Decree also makes reference to an opinion by the Italian Superior Institute of Health which it says found (i) that residues of genetically modified components (proteins) remain in the four products in question and (ii) that the technical documentation available does not examine the relevant GMOs in comparison to their conventional counterparts with regard to the presence of these components. Although the Decree reports the

[2025] Exhibit EC-157/At. 1.
[2026] Exhibit EC-157/At. 2.
[2027] Appellate Body Report, *Australia – Salmon*, footnote 69.
[2028] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1120.
[2029] Exhibit EC-157/At. 1.

ultimate conclusion of the Italian Superior Institute of Health that "there are no apparent risks to the health of humans or livestock from the consumption of derivatives of the aforementioned GMOs"[2030], the Decree states that this conclusion was reached in a context in which there were inadequacies in the applicable risk assessment procedures. The Decree further states that since it had been established that residues of modified components remain in the four products, the information available from the simplified procedure was also inadequate with regard to the risks arising from "environmental release" of the GMOs in question, or their products.

7.3186 In our view, it is clear that the Decree does not itself provide an "evaluation" of the potential for adverse effects on human or animal health arising from the presence of certain substances/components (toxins, additives, etc.) in the four products in question. Similarly, the Decree does not itself evaluate the likelihood of the establishment or spread of a pest due to the "environmental release" of the relevant GMOs or their products. We therefore consider that the Decree is not in itself a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3187 We turn next to the opinion by the Italian Superior Institute of Health of July 2000.[2031] In assessing the possible food safety risks associated with the consumption of the four maize products, the Institute comments on composition (noting an expressed presence of protein deriving from the genetic modifications), toxicity of the products of "extraneous" genes (including Bt toxin), herbicide residues and antibiotic resistance. The report concludes that "in the light of current scientific knowledge it is this Institute's opinion that there are no risks to human or animal health due to the consumption of derivatives of the GMOs indicated in the table".[2032] Finally, the Institute declined to express an opinion regarding the risk of possible "environmental release" of the GMOs in question, or of their products.

7.3188 In considering the Institute's opinion, we note that in relation to herbicide residues, the Institute stated that this issue would need to be "evaluated" by the Phyto-pharmaceutical Commission in order to determine whether regulatory action would be appropriate. Thus, it is apparent that the Institute's opinion does not itself evaluate the potential for any adverse effects. Regarding toxicity and antibiotic resistance, we note that the opinion draws conclusions regarding the potential for adverse effects from the results of available studies and tests. These studies and tests are not annexed to the opinion, however. The opinion merely indicates their results and critical conclusions.[2033] Hence, it is clear that the text of the opinion does not itself contain and provide all the information necessary to an evaluation of the potential for the relevant adverse effects to occur. Accordingly, we consider that the Institute's opinion constitutes, not a complete, self-contained, scientific evaluation of the potential for adverse effects on human or animal health due to toxicity and the development of antibiotic resistance, but only part of such an evaluation. We are therefore of the view that the Institute's opinion does not meet the definition of a risk assessment as provided in the second clause of Annex A(4). Moreover, since none of the studies or tests referenced or mentioned in the opinion were provided to us, we cannot, and do not, express a view on whether the opinion and these studies and tests taken together would satisfy the Annex A(4) definition of a "risk assessment".

7.3189 Regarding potential risks arising from the "environmental release" of the relevant GMOs or their products, we recall that the Institute's opinion explicitly states that it does not address such risks.

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[2030] *Ibid*.
[2031] Exhibit EC-157/At. 2.
[2032] *Ibid*.
[2033] It is pertinent to note that that the entirety of the discussion concerning toxicity and antibiotic resistance extends over no more than one page.

It follows that the opinion does not provide an assessment of such risks which would meet the definition of Annex A(4).

7.3190 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Italy to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3191 Furthermore, in connection with the documents relied on by Italy, we should also note the European Communities' argument that Italy's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Italian safeguard measure include the fact that, from Italy's perspective, relevant scientific evidence was or is insufficient We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" in paragraphs 7.3052-7.3053 above and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3192 We have found above that the documents provided by the Parties in relation to Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) on which Italy relied do not constitute a risk assessment. However, the European Communities contends that there is a document other than the documents relied on by Italy which constitutes a risk assessment for T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[2034] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to those conducted by the SCP.[2035] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3193 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Italy's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3194 We now turn to the question of whether, at the time of establishment of this Panel, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) was "based on" either the risk assessment of the lead CA or those conducted by the SCP.[2036]

7.3195 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the

[2034] EC reply to Panel question No. 107.

[2035] Exhibits EC-159/Ats. 1-2; EC-160/At. 1-2; EC-163/At. 1; CDA-82, CDA-83, CDA-84 and CDA-85; US-68 (referencing original SCP risk assessments); ARG-47 (referencing original SCP risk assessments).

[2036] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or those conducted by the SCP.

SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) and the risk assessments performed by the lead CA and the SCP in relation to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163);

(b) the European Communities or Italy did not explain, by reference to these risk assessments, how and why Italy assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Italy's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Italy's safeguard measure, which imposes a prohibition, and risk assessments which we understand found no grounds for considering that the use of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) endangers human health or the environment.

7.3196 Thus, in view of our conclusion that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) and recalling the fact that no other risk assessment which might reasonably support Italy's safeguard measure has been provided to us, we find that the Italian safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2037]

7.3197 We add that even if the favourable opinion[2038] by the Superior Institute of Health of July 2000 was considered to provide a risk assessment regarding the concerns over toxicity and development of antibiotic resistance, Italy's decision to prohibit the marketing of the four GM maize products at issue could not, in our view, be said to be based on the Institute's favourable opinion. The reasons which we have given above in relation to the risk assessments performed by the lead CA or the SCP apply, *mutatis mutandis*, also to the Institute's opinion.

[2037] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Italian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[2038] We recall that the Institute's conclusion was to the effect that there are no risks to human health due to the consumption of these products.

Overall conclusions

7.3198 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment.

(iii) DS293 (Argentina)[2039]

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize and Bt-11 maize (EC-163) is not based on a risk assessment.

7.3199 In view of our findings in the previous paragraph with regard to DS291 (United States), DS292 (Canada) and DS293 (Argentina), it is necessary to examine, in addition, whether the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

*(x) Luxembourg – Bt-176 maize*

7.3200 We now turn to Luxembourg's safeguard measure on Bt-176 maize. We recall that we must determine whether Luxembourg's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the document Luxembourg relies on to justify its safeguard measure meet the definition of a risk assessment.

[2039] We recall that unlike the complaints by the other Complaining Parties, Argentina's complaint with regard to the Italian safeguard measure covers only three products subject to the Italian decree of August 2000, *i.e.*, T25 maize, MON810 maize and Bt-11 maize.

"Risk assessment"

7.3201 We recall that only one document was submitted by the Parties in relation to Luxembourg's safeguard measure on Bt-176 maize, namely the Reasons document.[2040] Thus, we must determine whether this document constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

7.3202 As with Austria's safeguard measure for Bt-176 maize, given the concerns raised by Luxembourg in the context of Bt-176 maize, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for Luxembourg's measure on Bt-176 maize.

7.3203 In the Reasons document, Luxembourg alleges that Bt-176 maize poses risks in relation to the development of antibiotic resistance and the development of insect resistance to Bt toxin. Regarding the development of antibiotic resistance, the Reasons document refers to scientific advice from EC scientific committees and other scientific experts. Although Luxembourg acknowledges that these experts indicated that there was only a small risk that antibiotic resistance would develop due to gene transfer to bacteria in the gut of humans or animals, Luxembourg insists that a small risk exists, notably in situations where the maize in question is used as animal feed, and argues that there is a need for further study regarding the mechanism of gene transfer.

7.3204 With regard to the development of insect resistance to Bt toxin, the Reasons document refers to the "possible" emergence of insects resistant to the Bt toxin as "a real risk factor".[2041] It emphasizes the lack of understanding of the long-term impacts of Bt toxin on the evolution of insect resistance. It also refers to a case of development of insect resistance in the United States in the wake of the introduction of GM cotton with an insecticidal trait. The Reasons document argues in this respect that as long as the causes of the insect resistance in the United States have not been elucidated, Bt maize should not be cultivated.

7.3205 Thus, the Reasons document calls for, but does not itself provide, further evaluation of the mechanism of gene transfer which might lead to the development of antibiotic resistance and of the risk of development of insects resistant to Bt toxin. More particularly, the Reasons document does not make a further evaluation of the likelihood of the spread of diseases or target insects. Nor does it make a further evaluation of the potential for adverse effects on human or animal health arising from the presence of ARMG in food. Given this, we consider that the Reasons document does not meet the definition of a risk assessment as provided in Annex A(4).

7.3206 In the light of the foregoing, we conclude that the Reasons document, being the document relied on by Luxembourg to justify its safeguard measure, does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3207 Furthermore, in connection with the document relied on by Luxembourg, we should also note the European Communities' argument that Luxembourg's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of Luxembourg's safeguard measure include the fact that, from Luxembourg's perspective, relevant scientific evidence was or is insufficient We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

[2040] Exhibit EC-158/At. 9.
[2041] *Ibid*.

7.3208 We have found above that the only document which was provided by the Parties in relation to Luxembourg's safeguard measure on Bt-176 maize and which Luxembourg relied on does not constitute a risk assessment. However, the European Communities contends that there is a document other than the document relied on by Luxembourg which constitutes a risk assessment for Bt-176. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[2042] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or any of the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal Nutrition (SCAN) or the SCF.[2043] In any event, it is not in dispute that these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3209 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Luxembourg's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3210 We now turn to the question of whether, at the time of establishment of this Panel, Luxembourg's safeguard measure on Bt-176 maize was "based on" either the risk assessment of the lead CA or that conducted by the SCPE, the SCAN or the SCF.[2044]

7.3211 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Luxembourg's safeguard measure on Bt-176 maize and the risk assessments performed by the lead CA and the SCPE, the SCAN and the SCF in relation to Bt-176 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCPE, the SCAN or the SCF with regard to Bt-176 maize;

(b) the European Communities or Luxembourg did not explain, by reference to these risk assessments, how and why Luxembourg assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such

[2042] EC reply to Panel question No. 107.

[2043] Exhibits EC-158/Ats. 1-3; EC-158/At. 4; EC-158/At. 5; EC-158/At. 6.

[2044] As noted, we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCPE, the SCAN or the SCF.

uncertainties or constraints, Luxembourg's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Luxembourg's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Bt-176 maize will give rise to any adverse effects on human or animal health and the environment.

7.3212 Thus, in view of our conclusion that Luxembourg's safeguard measure on Bt-176 maize cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCPE, the SCAN or the SCF in relation to Bt-176 maize, and recalling the fact that no other risk assessment which might reasonably support Luxembourg's safeguard measure has been provided to us, we find that Luxembourg's safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2045]

Overall conclusions

7.3213 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment.

7.3214 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether Luxembourg's safeguard measure on Bt-176 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of Luxembourg's safeguard measure on Bt-176 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(d) Consistency with Article 5.7 of the *SPS Agreement* and final conclusion regarding consistency with Article 5.1 of the *SPS Agreement*

7.3215 We have found above that none of the relevant safeguard measures meets the requirements set out in the text of Article 5.1. As we have said, in view of this finding, it is necessary to go on to examine whether the safeguard measures are consistent with the requirements of Article 5.7 of the *SPS Agreement*.

[2045] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, Luxembourg's safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

7.3216 To recall, Article 5.7 provides as follows:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

7.3217 We have explained earlier that if we were to find that a safeguard measure is consistent with the requirements of Article 5.7, Article 5.1 would not be applicable and we would consequently need to conclude that the European Communities has not acted inconsistently with its obligations under Article 5.1. Conversely, if we were to find that a safeguard measure is inconsistent with the requirements of Article 5.7, Article 5.1 would be applicable and, in view of our finding that none of the safeguard measures meets the requirements set out in the text of Article 5.1, we would need to conclude that the European Communities has acted inconsistently with its obligations under Article 5.1 in respect of the relevant measure.

7.3218 Before embarking on an examination of the individual safeguard measures under Article 5.7, it is well to recall that the Appellate Body in *Japan – Agricultural Products II* found that there are four requirements in Article 5.7 that must be met in order for a Member to adopt and maintain a provisional SPS measure. More specifically, the Appellate Body stated that:[2046]

> "Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is:
>
> (1) imposed in respect of a situation where "relevant scientific information is insufficient"; and
>
> (2) adopted "on the basis of available pertinent information".
>
> Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:
>
> (1) "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and
>
> (2) 'review[s] the … measure accordingly within a reasonable period of time'."

7.3219 Furthermore, we note that, according to the Appellate Body, the four requirements contained in Article 5.7 are "clearly cumulative in nature".[2047] In other words, "[w]henever one of these four requirements is not met, the measure at issue is inconsistent with Article 5.7."[2048]

7.3220 The Appellate Body further stated that Article 5.7 reflects the precautionary principle, and that the precautionary principle as such has not been written into the *SPS Agreement* as a ground for

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[2046] Appellate Body Report, *Japan – Agricultural Products II*, para. 89. *See also* Appellate Body Report, *Japan – Apples*, para. 176. We note regarding the first requirement that the Appellate Body referred to "relevant scientific information" instead of "relevant scientific evidence".

[2047] Appellate Body Report, *Japan – Agricultural Products II*, para. 89.

[2048] *Ibid*.

justifying an SPS measure that is otherwise inconsistent with that Agreement.[2049] The European Communities asserts that each of the safeguard measures at issue in this dispute is based on the precautionary principle. Since we examine below whether the relevant safeguard measures are consistent with the requirements of Article 5.7, in view of the aforementioned statement by the Appellate Body, we see no need separately to examine the European Communities' argument that these measures are based on the precautionary principle.

7.3221 With this in mind, we now turn to examine the first member State safeguard measure, Austria's safeguard measure on T25 maize. As always, we begin with a summary of the Parties' main arguments.

*(i) Austria – T25 maize*

7.3222 The **United States** argues that the Austrian safeguard measure on T25 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on T25 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Austria did not warrant any change in the earlier risk assessment. *Third*, Austria has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Austria has sought to perform a risk assessment that would support its measure on T25 maize. *Finally*, the United States alleges that neither Austria nor the Commission have reviewed the Austrian safeguard measure within a reasonable period of time.

7.3223 **Canada** argues that a review of the Austrian safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or Austria to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3224 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

[2049] Appellate Body Report, *EC – Hormones*, para. 124.

7.3225 **Argentina** argues that the Austrian safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on T25 maize, including one which specifically rejected the information provided by Austria in support of the measure. *Second*, Austria did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Austria has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Austria did not review its safeguard measure.

7.3226 The **European Communities** argues that the Austrian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised".[2050]

7.3227 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2051] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3228 Applying these considerations to the Austrian safeguard measure on T25 maize, the European Communities submits that, having regard to the specific concerns of Austria's legislators in adopting that measure, Austria's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3229 Furthermore, the European Communities contends that Austria has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Austria and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

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[2050] EC first written submission, para. 604.

[2051] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

7.3230 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2052] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2053] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, *e.g.* life-terminating, damage to human health are concerned".[2054] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2055]

7.3231 The **Panel** notes that in presenting arguments with respect to the four requirements of Article 5.7, the Parties started with the first requirement, *i.e.* whether the Austrian safeguard measure was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". The Panel, too, will begin its analysis with the first requirement.[2056]

"Insufficiency of relevant scientific evidence"

7.3232 We recall that pursuant to the first requirement, a Member must not provisionally adopt an SPS measure except in a case "where relevant scientific evidence is insufficient". Before examining the Austrian safeguard measure in the light of this requirement, we need to address two issues: (i) whether the sufficiency of the scientific evidence must be assessed by reference to Austria's appropriate level of sanitary or phytosanitary protection and (ii) whether the sufficiency of the scientific evidence is to be judged at the time of adoption of the Austrian safeguard measure or at the

[2052] We recall that the US argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures be reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2053] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2054] Appellate Body Report, *EC – Hormones*, para. 124.

[2055] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the *Japan – Apples* case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2056] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

time of review by this Panel, *i.e.*, at the time this Panel's terms of reference were fixed. We will examine these issues in turn.

Relevance of the appropriate level of sanitary or phytosanitary protection from risks

7.3233 We recall the European Communities' contention in paragraph 7.3227 above that in assessing the sufficiency of relevant scientific evidence, regard must be had to the protection goals pursued by legislators. In considering this contention, we recall as an initial matter that the Appellate Body in *Japan – Apples* clarified the meaning of the phrase "where relevant scientific evidence is insufficient". According to the Appellate Body, the notion of "insufficiency" implies a relationship between the scientific evidence and something else. On that basis, the Appellate Body determined that "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*".[2057] It appears that in the Appellate Body's view scientific evidence could be considered to be insufficient in qualitative terms for instance when it is inconclusive or unreliable.[2058]

7.3234 The European Communities argues that the concept of "insufficiency" in Article 5.7 is "relational" and must, therefore refer to the matters of concern to the legislator. We are not persuaded by this argument. While the Appellate Body has said that the notion of "insufficiency" implies a "relationship" between the scientific evidence and something else, it nowhere said that the notion of "insufficiency" implies a relationship between the scientific evidence and the matters of concern to the legislator. The Appellate Body identified, and acknowledged the existence of, only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1.

7.3235 We note that the Appellate Body in *Japan – Apples* referred to the insufficiency of available scientific evidence to perform an "adequate" assessment of risks. The European Communities appears to rely on the Appellate Body's use of the term "adequate", for it argues that an "adequate" assessment of risks is one which is "adequate for the purposes of the legislator". The Appellate Body failed to define or explain the term "adequate". Moreover, the term "adequate" nowhere appears in Article 5.1, Article 5.7 or Annex A(4). In these circumstances, we are not convinced that we should attach much significance to this term.[2059] Indeed, the term "adequate" may have been intended as nothing more than a reference to the definition in Annex A(4). On this view, a risk assessment would be "adequate" if it meets the standard and definition provided in Annex A(4).

7.3236 If we were nonetheless to try to give independent meaning to the term "adequate", the second sentence of Article 5.7 appears to us to be instructive. That sentence makes clear that in circumstances where relevant scientific evidence is insufficient and a Member has provisionally adopted an SPS measure, the Member concerned must seek to obtain the additional information necessary for a "more objective assessment of risk". We have observed earlier that we take the phrase "a more objective assessment of risk", considered as a whole, to refer to a risk assessment which satisfies the definition provided in Annex A(4), or at least which is closer to satisfying the definition in Annex A(4) than consideration of "available pertinent information". Also, Article 5.1 requires SPS measures to be based on a risk assessment within the meaning of Annex A(4). On that basis, it can be

[2057] Appellate Body Report, *Japan – Apples*, para. 179.
[2058] *Ibid.*, para. 185.
[2059] This view is supported by the fact that three paragraphs later in its report on *Japan – Apples*, the Appellate Body dropped the term "adequate", referring only to "an assessment of risks, as required under Article 5.1 and as defined in Annex A". Appellate Body Report, *Japan – Apples*, para. 182.

argued that the Appellate Body's reference to "an *adequate* assessment of risks as required by Article 5.1 and as defined in Annex A" (emphasis added) should be understood as a reference to "a *more objective* assessment of risks as required by Article 5.1 and as defined in Annex A".

7.3237 Clearly, neither of the two above-noted interpretations of the term "adequate" supports the conclusion that in referring to an "adequate" risk assessment, the Appellate Body intended to suggest that a risk assessment had to be adequate for the purposes of a Member's legislator. The two above-noted interpretations support the conclusion that, in the view of the Appellate Body, relevant scientific evidence is insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). At any rate, this is the interpretation of the concept of "insufficiency" in Article 5.7 which we believe to be correct.

7.3238 The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. We would agree that it must be determined on a case-by-case basis whether the body of available scientific evidence is insufficient to permit the performance of a risk assessment. But we are not convinced that the protection goals pursued by a legislator are relevant to such a determination. The protection goals of a legislator may have a bearing on the question of which risks a Member decides to assess with a view to taking regulatory action, if necessary. And a legislator's protection goals are certainly relevant to the determination of the measure – or as the European Communities puts it, the "actions" – to be taken for achieving a Member's level of protection against risk. Yet there is no apparent link between a legislator's protection goals and the task of assessing the existence and magnitude of potential risks.

7.3239 We note that the European Communities defines a risk assessment which is adequate for the purposes of a Member's legislator as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised".[2060] We have already expressed the view that the question to be answered in an Article 5.7 inquiry is not whether relevant scientific evidence permits the performance of a risk assessment adequate for the purposes of a legislator, but whether it permits the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). Nonetheless, we must examine whether the kind of risk assessment the European Communities considers adequate is consistent with the kind of risk assessment required under Article 5.1 and defined in Annex A(4).

7.3240 We note in this respect that a risk assessment as required under Article 5.1 and as defined in Annex A(4) may set forth diverging scientific opinions coming from qualified and respected sources and, to that extent, need not necessarily inform a Member "unequivocally" about risks. A risk assessment as defined in Annex A(4) should normally address the "degree of precision", or level of confidence, with which the relevant risks can be, or have been, assessed and the circumstances in which the assessment may need to be "revised".[2061] Also, the "passage of time" may be a limiting

[2060] *Ibid.*

[2061] It is instructive to note what is stated in this regard in pertinent risk assessment techniques developed by relevant international organizations. Thus, the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* provide that "[c]onstraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner". Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (adopted in June/July 2003),

factor which might warrant a revision of an existing risk assessment. However, where a risk assessment has been performed, and that risk assessment meets the standard and definition of Annex A(4), it does not cease to be a risk assessment within the meaning of Annex A(4) merely because a particular Member judges that the risks have not been assessed with a "sufficient" degree of precision, that the assessment has not "withstood" the passage of time, and that it is "likely" that the assessment may need to be revised at some point in the future. If there are factors which affect scientists' level of confidence in a risk assessment they have carried out[2062], this may be taken into account by a Member in determining the measure to be applied for achieving its appropriate level of protection from risks. Thus, consistent with the foregoing remarks, we consider that it would be improper to apply the European Communities' definition of an "adequate" risk assessment for the purposes of an analysis of whether relevant scientific evidence is insufficient to perform a risk assessment. We observe that this view is consistent with risk assessment techniques established by relevant international organizations. For instance, the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* state that "[t]he report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors".[2063] Along similar lines, the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* state that "[r]isk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties".[2064] Similarly, the IPPC's ISPM #11 (2001) states in relevant part that "[t]he uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option".[2065] The quoted passage stayed the same in the 2004 version of ISPM #11, which applies specifically to living modified organisms.

7.3241 Based on its view that a risk assessment must be adequate for the purposes of a Member's legislator, the European Communities argues that a Member with a high appropriate level of protection may justifiably consider that the available body of scientific evidence is insufficient to permit the assessment of risks with a degree of precision which it would find adequate, while a Member with a lower appropriate level of protection may consider that the same body of evidence is sufficient to perform an adequate risk assessment. In other words, the European Communities argues that in determining whether relevant scientific evidence is insufficient within the meaning of Article 5.7, regard must be had to a Member's appropriate level of protection.

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Section III, Codex Procedural Manual, 14th edition, 2004, para. 23. Similarly, the IPPC's ISPM #11 (2001) states in relevant part that "[e]stimation of the probability of introduction of a pest and of its economic consequences involves many uncertainties. [...] It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used". IPPC, ISPM #11 : *Pest Risk Analysis for Quarantine Pests*, April 2001, para. 2.4. The quoted passage stayed the same in the 2004 version of ISPM #11, which applies specifically to living modified organisms. Finally, the principles of risk assessment of the OIE *Terrestrial Animal Health Code* provide in relevant part that "[r]isk assessments should document the uncertainties, the assumptions made, and the effect on these on the final risk estimate". OIE, *Terrestrial Animal Health Code*, 2002, Article 1.3.2.3, para. 5.

[2062] *E.g.*, a limited body of relevant scientific evidence may be such a factor.

[2063] Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex* Alimentarius (adopted in June/July 2003), Section III, Codex Procedural Manual, 14th edition, 2004, para. 25.

[2064] Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (adopted in June/July 2003), CAC/GL 44-2003, para. 18.

[2065] IPPC, ISPM #11: *Pest Risk Analysis for Quarantine Pests*, April 2001, para. 3.

7.3242 There can be no doubt that a Member's appropriate level of protection is relevant to determining the SPS measure to be applied, if any, to protect that Member from risks. Article 5.3 of the *SPS Agreement* refers to the determination of "the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from [...] risk", and Article 5.6 relates to the establishment or maintenance of "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection".

7.3243 In contrast, the definition of the term "risk assessment" in Annex A(4) does not indicate that a Member's appropriate level of protection is pertinent to an assessment of the existence and magnitude of risks.[2066] Also, Annex A(5) to the *SPS Agreement* states that the concept of the appropriate level of protection is referred to by some Members as the concept of the "acceptable level of risk". We do not think that scientists need to know a Member's "acceptable level of risk" in order to assess objectively the existence and magnitude of a risk.[2067] Furthermore, neither Article 5.2[2068] nor Article 5.3[2069] suggests that a Member's appropriate level of protection may be relevant to the assessment of risks.

7.3244 We note that Article 5.1 provides that SPS measures must be based on an assessment of risks which is "appropriate to the circumstances". The European Communities appears to suggest that an importing Member's appropriate level of protection is a relevant circumstance within the meaning of Article 5.1.[2070] In our view, an importing Member may not reject an existing risk assessment which meets the definition of Annex A(4) as not "appropriate to [its] circumstances" on the basis that this risk assessment indicates constraints or uncertainties, and that this would not enable the Member concerned to determine "with a sufficient degree of precision" whether a particular type of measure would in fact achieve its appropriate level of protection. As we have said, if there are factors which affect scientists' level of confidence in a risk assessment they have carried out, an importing Member may take this into account in determining the measure to be applied for achieving its appropriate level of protection.[2071]

7.3245 Finally, we note the European Communities' argument that the phrase "within a reasonable period of time" in the second sentence of Article 5.7 supports its view that the importing Member's appropriate level of protection is relevant to determining whether available scientific evidence is

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[2066] We note that Annex A(4) in part defines a "risk assessment" as "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied". We are not convinced that a Member's appropriate level of protection is relevant to identifying "the sanitary or phytosanitary measures which might be applied". In any event, even if this were the case, we do not see how this could affect whether an assessment of the existence and magnitude of risks could be carried out.

[2067] We note in this regard that in *Australia – Salmon* the Appellate Body also underlined the importance of distinguishing carefully "between the evaluation of 'risk' in a risk assessment and the determination of the appropriate level of protection". Appellate Body Report, *Australia – Salmon*, para. 125.

[2068] Article 5.2 provides that "[i]n the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment".

[2069] Article 5.3 provides in relevant part that "[i]n assessing the risk to animal or plant life or health [...], Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks".

[2070] EC reply to Panel question No. 107.

[2071] It should also be recalled that to the extent a risk assessment sets out a minority opinion from a qualified and respected source, an importing Member may also be justified in basing a measure to achieve its appropriate level of protection on that minority opinion.

insufficient within the meaning of Article 5.7 to perform a risk assessment. The second sentence of Article 5.7 requires that Members seek to obtain the information necessary for a more objective assessment of risk and review provisional SPS measures accordingly within a reasonable period of time. In *Japan – Agricultural Products II*, the Appellate Body stated that what constitutes a "reasonable period of time" depends, *inter alia*, on the difficulty of obtaining the information necessary for a more objective assessment of risk.[2072] We think that in cases where additional information obtained by a Member is objectively sufficient to perform "a more objective assessment of risk", the phrase "review [...] within a reasonable period of time" would not provide a justification for delaying the performance of such an assessment on the grounds that an assessment incorporating the additional information would not allow the importing Member to determine "with a sufficient degree of precision" whether a measure different from its provisional measure would achieve its appropriate level of protection. Here again, we consider that if there are factors which affect scientists' level of confidence in "a more objective assessment of risk" they have performed, the importing Member may take this into account when reviewing its provisional measure in the light of the "more objective assessment". Thus, we are unable to accept the European Communities' argument concerning the phrase "within a reasonable period of time".

7.3246 Based on the above considerations, we are unable to agree with the European Communities that in the context of Article 5.7 the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. More particularly, we do not agree that we need to have regard to Austria's appropriate level of protection in examining whether relevant scientific evidence was sufficient to perform a risk assessment for T25 maize as required under Article 5.1 and as defined in Annex A(4).

Time at which insufficiency of relevant scientific evidence is to be assessed

7.3247 We now turn to analyse the second issue, *i.e.*, whether the insufficiency of relevant scientific evidence, which is a prerequisite for invoking the exception under Article 5.7, is to be judged at the time of adoption of the Austrian safeguard measure or at the time this Panel's terms of reference were fixed.

7.3248 The first sentence of Article 5.7 provides that "[i]n cases where relevant scientific evidence is insufficient", a Member may provisionally "adopt" an SPS measure on the basis of available pertinent information. Thus, the text of the first sentence establishes a clear link between the required insufficiency of relevant scientific evidence and the adoption of a provisional SPS measure which is based on available pertinent information.

7.3249 The second sentence of Article 5.7 provides that "[i]n such circumstances", *i.e.*, in circumstances where an SPS measure has been provisionally adopted consistently with the requirements of the first sentence of Article 5.7, the relevant Member must seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time. It is apparent from the conjunction "[i]n such circumstances" as well as the nature of the requirements laid down in the second sentence of Article 5.7 that that sentence establishes under what conditions an SPS measure which has been provisionally adopted may be maintained.

7.3250 The Appellate Body appears to share the view that the first sentence of Article 5.7 is concerned with the adoption of provisional SPS measures while the second sentence is concerned with the maintenance of such measures. In *Japan – Agricultural Products II*, the Appellate Body

[2072] Appellate Body Report, *Japan – Agricultural Products II*, para. 93.

stated that "[p]ursuant to the first sentence of Article 5.7, a Member may provisionally *adopt* an SPS measure if this measure [meets the two requirements set out in the first sentence]" and that "[p]ursuant to the second sentence of Article 5.7, such a provisional measure may not be *maintained* unless the Member which adopted the measure [complies with the two requirements set out in the second sentence]".[2073] Subsequently, in *Japan – Apples*, the Appellate Body confirmed that the two requirements set out in the second sentence of Article 5.7 "relate to the *maintenance* of a provisional [SPS] measure and highlight the *provisional* nature of measures adopted pursuant to Article 5.7".[2074]

7.3251 Reinforcing our view that the first sentence of Article 5.7 relates to the adoption of provisional SPS measures, but not to their maintenance, is the immediate context of Article 5.7. Article 5.6 provides in relevant part that "when *establishing or maintaining* [SPS] measures to achieve the appropriate level of [...] protection, Members shall ensure that such measures are not more trade-restrictive than required" (emphasis added). Likewise, Article 5.8 stipulates in relevant part that "[w]hen a Member has reason to believe that a specific [SPS] measure *introduced or maintained* by another Member is constraining [...] its exports and the measure is not based on the relevant international standards, guidelines or recommendations [...], an explanation of the reasons for such [SPS] measure may be requested and shall be provided" (emphasis added). Since Articles 5.6 and 5.8 explicitly refer to the "maintenance" of SPS measures in addition to the "establishment" or "introduction" of SPS measures, we think it may be justifiably assumed that the absence of a reference to the "maintenance" of a provisional SPS measure in the first sentence is intentional, and that "maintenance" is indeed covered by the second sentence of Article 5.7.

7.3252 Article 2.2 of the *SPS Agreement* is also part of the context of the first sentence of Article 5.7. To recall, Article 2.2 states in part that SPS measures may not be "*maintained* without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5" (emphasis added). We note the absence of a reference to the "adoption" of SPS measures without sufficient scientific evidence. Logic suggests that if an SPS measure may not be maintained without sufficient scientific evidence, it may also not be adopted without sufficient scientific evidence. This view draws support from the first sentence of Article 5.7, which explicitly refers to the "adoption" of provisional SPS measures. We recall in this respect that Article 5.7 provides for a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. Having said this, we do not consider that, conversely, it may be deduced from the reference to the "maintenance" of an SPS measure in Article 2.2 that the first sentence of Article 5.7 implies a reference to the "maintenance" of a provisional SPS measure. As we have noted, we think that the second sentence of Article 5.7 sets forth the applicable requirements relating to the maintenance of a provisional SPS measure. Moreover, we have noted that in marked contrast with the first sentence of Article 5.7, other provisions of the same Article – we have identified Article 5.6 and Article 5.8 – explicitly refer to both the establishment, or introduction, of SPS measures in addition to their maintenance.

7.3253 Since the phrase "[i]n cases where relevant scientific evidence is insufficient" is part of the first sentence of Article 5.7, and since the above considerations lead us to conclude that the requirements contained in the first sentence relate only to the adoption of a provisional SPS measure, we are of the view that a determination of whether a particular case is a case "where relevant scientific evidence is insufficient" must be made by reference to the time the relevant provisional SPS measure was adopted.

7.3254 Consideration of the alternative view strengthens rather than undermines our view. Indeed, if it were assumed that, contrary to our view, it is to be assessed at the time of review by a panel whether

[2073] Appellate Body Report, *Japan – Agricultural Products II*, para. 89 (emphasis added).
[2074] Appellate Body Report, *Japan – Apples*, footnote 318 (emphasis in original).

"relevant scientific evidence is insufficient", the second sentence of Article 5.7 would effectively become redundant. If a Member invoking the exception set out in Article 5.7 had to demonstrate that at the time of review by a panel relevant scientific evidence was insufficient to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4), there would be no apparent need to require that Member to seek to obtain additional information and to review its provisional SPS measure; the Member concerned would have every incentive to do so even in the absence of a requirement as it might be called on to defend its measure at any time.[2075] What is more, if that Member succeeded in demonstrating that relevant scientific evidence was insufficient, we fail to see what purpose would be served by requiring that Member to demonstrate, in addition, that at some earlier point in time it had sought additional information and reviewed its measure.

7.3255 We have concluded that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted. This conclusion warrants some elaboration, to avoid possible misinterpretation. *First of all*, we are not suggesting that evidence which establishes that, at some point between the time of adoption of a provisional SPS measure and the time a panel's terms of reference were fixed, relevant scientific evidence became sufficient, or was still insufficient, to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4), is *a priori* irrelevant to an Article 5.7 inquiry. To the contrary, such evidence may be relevant to an inquiry under the second sentence of Article 5.7. It may shed light on whether the Member invoking the exception under Article 5.7 has complied with the requirement to "seek to obtain the additional information necessary for a more objective risk assessment". Alternatively, such evidence may be relevant to a determination of whether the Member invoking the exception under Article 5.7 has conducted a "review" of its provisional measure "within a reasonable period of time".

7.3256 *Secondly*, there is no incongruity between our approach to the European Communities' claim under Article 5.7 and our approach to the Complaining Parties' claim under Article 5.1 and their consequential claim under Article 2.2. It is true that in analysing these latter claims, we have reviewed the situation as it existed at the time the Panel's terms of reference were fixed. However, our approach to Article 5.7 is in keeping with, and gives meaning to, the two sentences of Article 5.7. As we see it, a Member maintaining a provisional SPS measure cannot make a successful claim of justification under Article 5.7 if that measure has not been adopted consistently with the requirements of the first sentence of Article 5.7. Furthermore, if in our analysis we reach the issue of whether the Austrian safeguard measure meets the requirements of the second sentence of Article 5.7, which relates to the maintenance of a provisional SPS measure, we will examine this issue in the light of the situation as it existed when our terms of reference were set. In other words, in the context of any inquiry under the second sentence of Article 5.7, we will follow the approach we adopted in respect of the Complaining Parties' claims under Article 5.1 and 2.2.

7.3257 *Thirdly*, our approach does not have as a consequence that a provisional SPS measure which has been adopted consistently with the requirements of the first sentence of Article 5.7 may be maintained indefinitely. The requirement in the second sentence of Article 5.7 that a Member "review" a provisional SPS measure in our view implies that once sufficient relevant scientific evidence has been obtained and a risk assessment meeting the definition of Annex A(4) has been

[2075] In contrast, if, as we think, the sufficiency of scientific evidence is to be assessed at the time a provisional SPS measure was adopted, a Member which could demonstrate that, at the time it adopted its provisional SPS measure, relevant scientific evidence was insufficient would not have an obvious incentive to seek additional information and review its measure in the absence of a requirement to do so. Our view gives purpose to the inclusion of such explicit requirements in the second sentence of Article 5.7.

carried out[2076], the provisional SPS measure must be withdrawn or modified if it cannot be "based on" the risk assessment in question. We note in this regard that the dictionary defines the noun "review" as "a formal assessment of something with the intention of instituting change if necessary".[2077] We also recall that the Appellate Body in *Japan – Apples* observed that the requirement to review provisional SPS measures "highlights the *provisional* nature of measures adopted pursuant to Article 5.7".[2078] This observation implies that a Member is required to withdraw or modify a provisional measure if the review establishes that the measure is no longer justified. Indeed, were it otherwise, the requirement to review a provisional SPS measure would be inconsequential and meaningless.

*(ii) Austria's safeguard measure on T25 maize*

7.3258 Turning now to Austria's safeguard measure on T25 maize, we note the Complaining Parties' argument that relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Austrian safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by Austria in support of its measure.

7.3259 We recall that Austria adopted its safeguard measure on T25 maize in April 2000. Following Austria's notification of the measure, the Commission requested the SCP to analyse the information provided by Austria in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of November 2000 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessment which it had carried out in the context of the EC approval procedure concerning T25 maize.[2079] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Austria and confirmed its original risk assessment. [2080]

7.3260 We have found above that both the SCP opinions delivered in the context of relevant EC approval procedures – the original assessments– and the SCP opinions delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2081] We recall in this regard that the European Communities does not suggest otherwise.[2082] In the light of this, we agree with the

[2076] We recall that a risk assessment as required under Article 5.1 and as defined in Annex A(4) could also be carried out by another Member or an international organization.

[2077] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1225.

[2078] Appellate Body Report, *Japan – Apples*, footnote 318 (emphasis in original).

[2079] Exhibits US-56; CDA-77 and 87; ARG-45 and ARG-46.

[2080] Exhibits US-56 (referencing original SCP assessment); CDA-75 and -87; ARG-45 and -46 (referencing original SCP assessment).

[2081] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2082] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that Austria may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "[c]ould set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*,

Complaining Parties that the SCP's review assessment of T25 maize, and the SCP's original assessment of T25 maize (which, as noted, was confirmed by the SCP's review assessment), serves to demonstrate that at the time of adoption of the Austrian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the Complaining Parties have established a presumption that Austria's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2083]

7.3261 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Austria's safeguard measure on T25 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3262 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Austrian safeguard measure on T25 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the Austrian safeguard measure on T25 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment, the Panel reaches the final conclusion

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para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of T25 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2083] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Austrian safeguard measure on T25 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(iii) Austria – Bt-176 maize*

7.3263 We now turn to Austria's safeguard measure applied with respect to Bt-176 maize. We note the arguments of the Parties in respect of this measure.

7.3264 The **United States** argues that the Austrian safeguard measure on Bt-176 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Bt-176 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCF and the Scientific Committee for Pesticides, Food and Animal Nutrition (SCPE) reviewed the safeguard measure and concluded that the information provided by Austria did not warrant any change in the earlier risk assessment. *Third*, Austria has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Austria has sought to perform a risk assessment that would support its measure on Bt-176 maize. *Finally*, the United States alleges that neither Austria nor the Commission have reviewed the Austrian safeguard measure within a reasonable period of time.

7.3265 **Argentina** argues that the Austrian safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on Bt-176 maize, including one which specifically rejected the information provided by Austria in support of the measure. *Second*, Austria did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Austria has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Austria did not review its safeguard measure.

7.3266 The **European Communities** argues that the Austrian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a

reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2084]

7.3267 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2085] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3268 Applying these considerations to the Austrian safeguard measure on Bt-176 maize, the European Communities submits that, having regard to the specific concerns of Austria's legislators in adopting that measure, Austria's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3269 *Second*, the European Communities contends that Austria has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Austria and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3270 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2086] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstance may justify a Member requiring a relatively long period of time to review its provisional measure.[2087] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2088] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future

[2084] EC first written submission, para. 604.

[2085] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2086] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2087] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2088] Appellate Body Report, *EC – Hormones*, para. 124.

consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2089]

"Insufficiency of relevant scientific evidence"

7.3271 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2090] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Austria's safeguard measure on Bt-176 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Austrian safeguard measure, since risk assessments were conducted by EC scientific committees on the basis of the information provided by Austria in support of its measure.

7.3272 We recall that Austria adopted its safeguard measure on Bt-176 maize in February 1997. Following Austria's notification of the measure, the Commission requested the SCF, the Scientific Committee for Animal Nutrition (SCAN) and the Scientific Committee for Pesticides (SCPE) to analyse the information provided by Austria in support of its measure in order to determine whether this information would cause these Committees to consider that the product constituted a risk to human health or the environment. The SCF in its opinion of March 1997, the SCAN in its opinion of April 1997 and the SCPE in its opinion of May 1997 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessments which they had carried out in the context of the EC approval procedure concerning Bt-176 maize.[2091]

7.3273 We have found above that both the opinions by EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of

[2089] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2090] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2091] Exhibits US-57, -58 and -66; ARG-43.

Annex A(4) and Article 5.1 of the *SPS Agreement*.[2092] We recall in this regard that the European Communities does not suggest otherwise[2093]. In the light of this, we agree with the United States and Argentina that the 1997 SCF, SCAN and SCPE review assessments of Bt-176 maize, and the SCF, SCAN and SCPE original assessments of Bt-176 maize (which, as noted, were confirmed by the review assessments), serve to demonstrate that at the time of adoption of the Austrian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Argentina have established a presumption that Austria's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities[2094].

7.3274 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Austria's safeguard measure on Bt-176 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3275 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Austrian safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion

[2092] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2093] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessments. It may be that in making this argument the European Communities meant to refer to the original risk assessments by the SCF, the SCAN and the SCPE. However, the fact that Austria may have disagreed with these' original assessments, and possibly also with the subsequent review assessment by the SCP, would not imply that these committees' assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the original and review assessments of Bt-176 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2094] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Austrian safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(iv) Austria – MON810 maize*

7.3276 We now turn to Austria's safeguard measure applied with respect to MON810 maize. We note the arguments of the Parties in respect of this measure.

7.3277 The **United States** argues that the Austrian safeguard measure on MON810 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on MON810 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Austria did not warrant any change in the earlier risk assessment. *Third*, Austria has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Austria has sought to perform a risk assessment that would support its measure on MON810 maize. *Finally*, the United States alleges that neither Austria nor the Commission have reviewed the Austrian safeguard measure within a reasonable period of time.

7.3278 **Argentina** argues that the Austrian safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on MON810 maize, including one which specifically rejected the information provided by Austria in support of the measure. *Second*, Austria did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Austria has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Austria did not review its safeguard measure.

7.3279 The **European Communities** argues that the Austrian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European

Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2095]

7.3280 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2096] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3281 Applying these considerations to the Austrian safeguard measure on MON810 maize, the European Communities submits that, having regard to the specific concerns of Austria's legislators in adopting that measure, Austria's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3282 *Second*, the European Communities contends that Austria has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Austria and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3283 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2097] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstance may justify a Member requiring a relatively long period of time to review its provisional measure.[2098] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2099] The European Communities differentiates the present case from

[2095] EC first written submission, para. 604.

[2096] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2097] We recall that the United States' argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2098] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2099] Appellate Body Report, *EC – Hormones*, para. 124.

*Japan - Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2100]

"Insufficiency of relevant scientific evidence"

7.3284 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2101] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Austria's safeguard measure on MON810 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Austrian safeguard measure, since risk assessments were conducted by the EC scientific committees on the basis of the information provided by Austria in support of its measure.

7.3285 We recall that Austria adopted its safeguard measure on MON810 maize in June 1999. Following Austria's notification of the measure, the Commission requested the SCP to analyse the information provided by Austria in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of September 1999 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessment which it had carried out in the context of the EC approval procedure concerning MON810 maize.[2102] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Austria and confirmed its original risk assessment.

7.3286 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of

[2100] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the *Japan – Apples* case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2101] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2102] Exhibits US-55 and ARG-44.

Annex A(4) and Article 5.1 of the *SPS Agreement*.[2103] We recall in this regard that the European Communities does not suggest otherwise.[2104] In the light of this, we agree with the United States and Argentina that the SCP's 1999 review assessment of MON810 maize, and the SCP's original assessment of MON810 maize (which, as noted, were confirmed by the review assessments), serve to demonstrate that at the time of adoption of the Austrian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Argentina have established a presumption that Austria's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2105]

7.3287 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Austria's safeguard measure on MON810 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3288 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Austrian safeguard measure on MON810 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

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[2103] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2104] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that Austria may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of MON810 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2105] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Austrian safeguard measure on MON810 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(v) France – MS1/RF1 oilseed rape (EC-161)*

7.3289 We now turn to France's safeguard measure applied with respect to MS1/RF1 oilseed rape (EC-161). We note the arguments of the Parties in respect of this measure.

7.3290 The **United States** argues that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on MS1/RF1 oilseed rape (EC-161). *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by France did not warrant any change in the earlier risk assessment. *Third*, France has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that France has sought to perform a risk assessment that would support its measure on MS1/RF1 oilseed rape (EC-161). *Finally*, the United States alleges that neither France nor the Commission have reviewed the French safeguard measure within a reasonable period of time.

7.3291 **Canada** argues that a review of the French safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or France to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3292 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence

of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3293 The **European Communities** argues that the French safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2106]

7.3294 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2107] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3295 Applying these considerations to the French safeguard measure on MS1/RF1 oilseed rape (EC-161), the European Communities submits that, having regard to the specific concerns of France's legislators in adopting that measure, France's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3296 *Second*, the European Communities contends that France has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both France and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3297 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and

[2106] EC first written submission, para. 604.

[2107] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

member State levels.[2108] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2109] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2110] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2111]

"Insufficiency of relevant scientific evidence"

7.3298 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2112] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Canada argue in this regard that in the case of France's safeguard measure on MS1/RF1 oilseed rape (EC-161), relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the French safeguard measure, since risk assessment were conducted by EC scientific committees on the basis of the information provided by France in support of its measure.

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[2108] We recall that the United States' argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2109] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2110] Appellate Body Report, *EC – Hormones*, para. 124.

[2111] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2112] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

7.3299 We recall that France adopted its safeguard measure on MS1/RF1 oilseed rape (EC-161) in November 1998. Following France's notification of the measure, the Commission requested the SCP to analyse the information provided by France in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health and the environment. The SCP in its opinion of May 1999 concluded that the information provided by France did not change the environmental assessment provided by the SCP in 1998 in the context of the approval procedure concerning a similar hybrid oilseed rape, MS8/RF3 oilseed rape.[2113] Thus, as we understand it, the SCP effectively reviewed its earlier risk assessment for MS8/RF3 oilseed rape in the light of the information presented by France and confirmed that assessment.

7.3300 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2114] We recall in this regard that the European Communities does not suggest otherwise.[2115] In the light of this, we agree with the United States and Canada that the SCP's 1999 review assessment of MS1/RF1 oilseed rape (EC-161), serves to demonstrate that at the time of adoption of the French safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Canada have established a presumption that France's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2116]

7.3301 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that France's safeguard measure on MS1/RF1 oilseed rape (EC-161) was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

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[2113] We recall that the SCP was not consulted by the Commission before MS1/RF1 oilseed rape was approved, hence the SCP's reliance on the assessment concerning MS8/RF3 oilseed rape. Exhibits US-61 and CDA-69.

[2114] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2115] It is pertinent to recall in this context that in defending the French safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that France acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment with regard to MS8/RF3 oilseed rape. However, the fact that France may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the relevant SCP assessments of MS1/RF1 oilseed rape are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2116] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

Overall conclusions

7.3302 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(vi) France – Topas oilseed rape*

7.3303 We now turn to France's safeguard measure applied with respect to Topas oilseed rape. We recall the arguments of the Parties in respect of this measure.

7.3304 The **United States** argues that the French safeguard measure on Topas oilseed rape fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Topas oilseed rape. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by France did not warrant any change in the earlier risk assessment. *Third*, France has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that France has sought to perform a risk assessment that would support its measure on Topas oilseed rape. *Finally*, the United States alleges that neither France nor the Commission have reviewed the French safeguard measure within a reasonable period of time.

7.3305 **Canada** argues that a review of the French safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own

scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or France to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3306 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3307 The **European Communities** argues that the French safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2117]

7.3308 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2118] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

[2117] EC first written submission, para. 604.

[2118] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

7.3309 Applying these considerations to the French safeguard measure on Topas oilseed rape, the European Communities submits that, having regard to the specific concerns of France's legislators in adopting that measure, France's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3310 *Second*, the European Communities contends that France has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both France and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3311 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2119] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2120] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2121] The European Communities differentiates the present case from *Japan - Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2122]

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[2119] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2120] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2121] Appellate Body Report, *EC – Hormones*, para. 124.

[2122] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

"Insufficiency of relevant scientific evidence"

7.3312 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2123] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Canada argue in this regard that in the case of France's safeguard measure on Topas oilseed rape, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the French safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by France in support of its measure.

7.3313 We recall that France adopted its safeguard measure on Topas oilseed rape in November 1998. Following France's notification of the measure, the Commission requested the SCP to analyse the information provided by France in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of May 1999 concluded that the information provided by France did not constitute new scientific information which would change the original risk assessment carried out by the SCP in the context of the EC approval procedure concerning Topas oilseed rape.[2124] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by France and confirmed its original risk assessment.

7.3314 We have found above that both the SCP opinions delivered in the context of relevant EC approval procedures – the original assessments – and the SCP opinions delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. [2125] We recall in this regard that the European Communities does not suggest otherwise.[2126] In the light of this, we agree with the United States and Canada that the SCP's 1999 review assessment of Topas oilseed rape and the SCP's original assessment of Topas oilseed rape (which, as noted, was confirmed by the SCP's review

[2123] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2124] Exhibits US-62; CDA-65.

[2125] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2126] It is pertinent to recall in this context that in defending the French safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that France acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that France may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of Topas oilseed rape are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

assessment), serve to demonstrate that at the time of adoption of the French safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Canada have established a presumption that France's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2127]

7.3315 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that France's safeguard measure on Topas oilseed rape was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3316 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the French safeguard measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the French safeguard measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(vii) Germany – Bt-176 maize*

7.3317 We now turn to Germany's safeguard measure applied with respect to Bt-176 maize. We recall the arguments of the Parties in respect of this measure.

[2127] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

7.3318 The **United States** argues that the German safeguard measure on Bt-176 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Bt-176 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Germany did not warrant any change in the earlier risk assessment. *Third*, Germany has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Germany has sought to perform a risk assessment that would support its measure on Bt-176 maize. *Finally*, the United States alleges that neither Germany nor the Commission have reviewed the German safeguard measure within a reasonable period of time.

7.3319 **Argentina** argues that the German safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on Bt-176 maize, including one which specifically rejected the information provided by Germany in support of the measure. *Second*, Germany did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Germany has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Germany did not review its safeguard measure.

7.3320 The **European Communities** argues that the German safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2128]

7.3321 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2129] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

[2128] EC first written submission, para. 604.

[2129] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

7.3322 Applying these considerations to the German safeguard measure on Bt-176 maize, the European Communities submits that, having regard to the specific concerns of Germany's legislators in adopting that measure, Germany's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3323 *Second*, the European Communities contends that Germany has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Germany and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3324 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2130] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstance may justify a Member requiring a relatively long period of time to review its provisional measure.[2131] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2132] The European Communities differentiates the present case from *Japan-Apples*: arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2133]

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[2130] We recall that the United States' arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. *See* US second written submission, para. 100.

[2131] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2132] Appellate Body Report, *EC – Hormones*, para. 124.

[2133] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

"Insufficiency of relevant scientific evidence"

7.3325 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2134] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Germany's safeguard measure on Bt-176 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the German safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by Germany in support of its measure.

7.3326 We recall that Germany adopted its safeguard measure on Bt-176 maize in March 2000. Following Germany's notification of the measure, the Commission requested the SCP to analyse the information provided by Germany in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of September 2000 concluded that the information provided by Germany did not constitute new scientific information which would change the original risk assessment which the SCPE had carried out in the context of the EC approval procedure concerning Bt-176 maize.[2135] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Germany and confirmed its original risk assessment.

7.3327 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2136] We recall in this regard that the European Communities does not suggest otherwise.[2137] In the light of this, we agree with the United States and Argentina that the SCP's 2000 review assessment of Bt-176 maize, and the SCPE's original

[2134] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2135] Exhibits US-66; ARG-43.

[2136] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2137] It is pertinent to recall in this context that in defending the German safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Germany acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCPE's original risk assessment. However, the fact that Germany may have disagreed with the SCPE's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of Bt-176 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

assessment of Bt-176 maize (which, as noted, was confirmed by the SCP's review assessment), serve to demonstrate that at the time of adoption of the German safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Argentina have established a presumption that Germany's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2138]

7.3328 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Germany's safeguard measure on Bt-176 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3329 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the German safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the German safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(viii) Greece – Topas oilseed rape*

7.3330 We now turn to Greece's safeguard measure applied with respect to Topas oilseed rape. We recall the arguments of the Parties in respect of this measure.

[2138] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the German safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure

7.3331 The **United States** argues that the Greek safeguard measure on Topas oilseed rape fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Topas oilseed rape. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Greece did not warrant any change in the earlier risk assessment. *Third*, Greece has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Greece has sought to perform a risk assessment that would support its measure on Topas oilseed rape. *Finally*, the United States alleges that neither Greece nor the Commission have reviewed the Greek safeguard measure within a reasonable period of time.

7.3332 **Canada** argues that a review of the Greek safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or France to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3333 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3334 The **European Communities** argues that the Greek safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2139]

[2139] EC first written submission, para. 604.

7.3335 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2140] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3336 Applying these considerations to the Greek safeguard measure on Topas oilseed rape, the European Communities submits that, having regard to the specific concerns of Greece's legislators in adopting that measure, Greece's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3337 *Second*, the European Communities contends that Greece has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Greece and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3338 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2141] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2142] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2143] The European Communities differentiates the present case from *Japan - Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere

[2140] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2141] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2142] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2143] Appellate Body Report, *EC – Hormones*, para. 124.

theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2144]

"Insufficiency of relevant scientific evidence"

7.3339 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2145] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Canada argue in this regard that in the case of Greece's safeguard measure on Topas oilseed rape, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Greek safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by Greece in support of its measure.

7.3340 We recall that Greece adopted its safeguard measure on Topas oilseed rape in September 1998. Following Greece's notification of the measure, the Commission requested the SCP to analyse the information provided by Greece in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of May 1999 concluded that the information provided by Greece did not constitute new scientific information which would change the original risk assessment carried out by the SCP in the context of the EC approval procedure concerning Topas oilseed rape.[2146] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Greece and confirmed its original risk assessment.

7.3341 We have found above that both the SCP opinions delivered in the context of relevant EC approval procedures – the original assessments – and the SCP opinions delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2147] We recall in this regard that the European Communities does not suggest otherwise.[2148] In the light of this, we agree with the

[2144] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2145] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2146] Exhibits US-70; CDA-73.

[2147] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2148] It is pertinent to recall in this context that in defending the Greek safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Greece acted on the basis of new scientific information which presented a view divergent from the mainstream scientific

United States and Canada that the SCP's 1999 review assessment of Topas oilseed rape, and the SCP's original assessment of Topas oilseed rape (which, as noted, was confirmed by the SCP's review assessment), serve to demonstrate that at the time of adoption of the Greek safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Canada have established a presumption that Greece's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2149]

7.3342 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Greece's safeguard measure on Topas oilseed rape was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3343 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Greek safeguard measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the Greek safeguard

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opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that Greece may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of Topas oilseed rape are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2149]In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Greek safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(ix) Italy – T25 maize, MON810 maize, MON809 maize, Bt-11 maize (EC-163)*

7.3344 We now turn to Italy's safeguard measure applied with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We recall the arguments of the Parties in respect of this measure.

7.3345 The **United States** argues that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on the products concerned. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCF reviewed the safeguard measure and concluded that the information provided by Italy did not warrant any change in the earlier risk assessment. *Third*, Italy has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Italy has sought to perform a risk assessment that would support its measure on the products concerned. *Finally*, the United States alleges that neither Italy nor the Commission have reviewed the French safeguard measure within a reasonable period of time.

7.3346 **Canada** argues that a review of the Italian safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or Italy to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3347 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3348 **Argentina** argues that the Italian safeguard measure[2150] does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on the products concerned, including one which specifically rejected the information provided by Italy in support of the measure. *Second*, Italy did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Italy has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Italy did not review its safeguard measure.

7.3349 The **European Communities** argues that the Italian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.

7.3350 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2151] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3351 Applying these considerations to the Italian safeguard measure on the products concerned, the European Communities submits that, having regard to the specific concerns of Italy's legislators in adopting that measure, Italy's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3352 *Second*, the European Communities contends that Italy has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European

[2150] We recall that unlike the complaints by the other Complaining Parties, Argentina's complaint with regard to the Italian safeguard measure covers only three products subject to the Italian decree of August 2000, *i.e.*, T25 maize, MON810 maize and Bt-11 maize.

[2151] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

Communities argues that both Italy and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3353 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2152] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2153] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2154] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2155]

"Insufficiency of relevant scientific evidence"

7.3354 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2156] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The Complaining Parties argue in this regard that in the case of Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), relevant scientific evidence could not

[2152] We recall that the United States' argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

[2153] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2154] Appellate Body Report, *EC – Hormones*, para. 124.

[2155] The European Communities notes that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2156] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

have been insufficient to conduct a risk assessment at the time of adoption of the Italian safeguard measure, since a risk assessment was conducted by the SCF on the basis of the information provided by Italy in support of its measure.

7.3355 We recall that Italy adopted its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) in August 2000. Following Italy's notification of the measure, the Commission requested the SCF to analyse the information provided by Italy in support of its measure in order to determine whether this information would cause the SCF to consider that the products in question constituted a risk to human health. The SCF in its opinion of September 2000 concluded that the information provided by Italy did not provide grounds for considering that the use of the products in question endangers human health. Thus, as we understand it, the SCF effectively confirmed the original risk assessments carried out by the SCP in the context of the EC approval procedures concerning the products concerned.

7.3356 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. [2157] We recall in this regard that the European Communities does not suggest otherwise.[2158] In the light of this, we agree with the Complaining Parties that the SCF's 2000 review assessment of the products concerned[2159], and the SCF's original assessment of the products concerned (which, as noted, was confirmed by the SCF's review assessment), serve to demonstrate that at the time of adoption of the Italian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the Complaining Parties have established a presumption that Italy's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2160]

7.3357 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been

[2157] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2158] It is pertinent to recall in this context that in defending the Italian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Italy acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessments. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessments. However, the fact that Italy may have disagreed with the SCP's original risk assessments, and possibly also with the SCF's subsequent review assessment, would not imply that these review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the original and review assessments of the products concerned are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2159] Exhibits US-68; CDA-86 and ARG-47.

[2160] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Italian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

established that Italy's safeguard measure on the products concerned was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3358 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Italian safeguard measure on T25 maize, MON810 maize and Bt-11 maize (EC-163) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

*(x) Luxembourg – Bt-176 maize*

7.3359 We now turn to Luxembourg's safeguard measure applied with respect to Bt-176 maize. We recall the arguments of the Parties in respect of this measure.

7.3360 The **United States** argues that Luxembourg's safeguard measure on Bt-176 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Bt-176 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCF and the Scientific Committee for Pesticides reviewed the safeguard measure and concluded that the information provided by Luxembourg did not warrant any change in the earlier risk assessment. *Third*, Luxembourg has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Luxembourg has sought to perform a risk assessment that would support its measure on Bt-176 maize. *Finally*, the United States alleges that neither Luxembourg nor the Commission have reviewed Luxembourg's safeguard measure within a reasonable period of time.

7.3361 **Argentina** argues that Luxembourg's safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on Bt-176 maize, including one which specifically rejected the information provided by Luxembourg in support of the measure. *Second*, Luxembourg did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Luxembourg has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Luxembourg did not review its safeguard measure.

7.3362 The **European Communities** argues that Luxembourg's safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.

7.3363 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific

evidence is insufficient, and that a measure is warranted.[2161] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3364 Applying these considerations to the Luxembourg safeguard measure on Bt-176 maize, the European Communities submits that, having regard to the specific concerns of Luxembourg's legislators in adopting that measure, Luxembourg's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3365 Furthermore, the European Communities contends that Luxembourg has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Luxembourg and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3366 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2162] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2163] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2164] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2165]

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[2161] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2162] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

[2163] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2164] Appellate Body Report, *EC – Hormones*, para. 124.

[2165] The European Communities notes that "[t]he present case is, for example, very different from the circumstances of the *Japan – Apples* case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case.

"Insufficiency of relevant scientific evidence"

7.3367 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2166] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Luxembourg's safeguard measure on Bt-176 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of Luxembourg's safeguard measure, since risk assessments were apparently conducted by EC scientific committees on the basis of the information provided by Luxembourg in support of its measure.[2167]

7.3368 We recall that Luxembourg adopted its safeguard measure on Bt-176 maize in February 1997. Following Luxembourg's notification of the measure, the Commission apparently did not request the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal Nutrition (SCAN) and the SCF to analyse the information provided by Luxembourg in support of its measure in order to determine whether this information would cause these Committees to consider that the product constituted a risk to human health or the environment. However, in response to a question from the Panel, the European Communities indicated that the Commission relied on the opinions provided by these committees in relation to Austria's safeguard measure on Bt-176 maize.[2168] To recall, the SCF in its opinion of March 1997, the SCAN in its opinion of April 1997 and the SCPE in its opinion of May 1997 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessments which they had carried out in the context of the EC approval procedure concerning Bt-176 maize.[2169]

7.3369 We have found above that both the opinions by EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2170] We recall in this regard that the European Communities does not suggest otherwise. [2171] In the light of this, we consider that the 1997 SCF,

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GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2166] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2167] The United States and Argentina have provided a document indicating that EC scientific committees were consulted on Luxembourg's safeguard measure. Exhibits US-107; ARG-6. The United States has indicated, however, that it was unable to locate any opinion by an EC scientific committee on Luxembourg's safeguard measure.

[2168] EC reply to Panel question No. 106.

[2169] Exhibits US-57, -58 and -66; ARG-43.

[2170] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2171] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessments. It may be that in making this argument the European Communities meant to refer to the original risk assessments by the SCF, the SCAN and the SCPE. However,

SCAN and SCPE review assessments of Bt-176 maize, and the SCF, SCAN and SCPE original assessments of Bt-176 maize (which, as noted, were confirmed by the review assessments), serve to demonstrate that at the time of adoption of Luxembourg's safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that these review assessments establish a presumption that Luxembourg's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2172]

7.3370 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Luxembourg's safeguard measure on Bt-176 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3371 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that Luxembourg's safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that Luxembourg's safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

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the fact that Austria may have disagreed with these' original assessments, and possibly also with the subsequent review assessment by the SCP, would not imply that these committees' assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the original and review assessments of Bt-176 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2172]In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, Luxembourg's safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure

> In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(e) Consistency with Article 5.6 of the *SPS Agreement*

7.3372 The Panel now turns to address Canada's and Argentina's claims of inconsistency under Article 5.6 of the *SPS Agreement*.

7.3373 We recall that Article 5.6 provides:

> "Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."

7.3374 **Canada** argues the EC member State safeguard measures are inconsistent with Article 5.6 because they are more trade-restrictive than required to achieve the EC's appropriate level of protection. The fact that Article 2.2 includes the phrase that measures should be "applied only to the extent necessary to protect human, animal or plant life or health" highlights the relationship between Article 2.2 and Article 5.6. Given this relationship, and the fact that Article 5.6 is a more specific expression of the general obligation found in the clause in Article 2.2, a measure that is found to be in violation of Article 5.6 must also be presumed to violate Article 2.2. Therefore, these measures must also be presumed to violate Article 2.2.

7.3375 **Argentina** argues that (a) the EC member States had alternative sanitary or phytosanitary measures available, other than bans; (b) it was possible to achieve an appropriate level of protection using these alternative measures; and (c) these alternative measures would have been significantly less restrictive than a ban on biotech agricultural products already approved by the European Communities. Therefore, Argentina contends that the bans at the level of some member States violate Article 5.6 of the *SPS Agreement*. Argentina also argues, however, that in the interests of procedural economy a finding by the Panel that the relevant member State safeguard measures are inconsistent with Articles 5.1 and 2.2 will obviate the need for a further finding by the Panel that the safeguard measures are inconsistent with Article 5.6.

7.3376 The **European Communities** argues that Article 5.6 is not relevant to the specific rule provided for in Article 5.7. The appropriate level of protection referred to in Article 5.6 refers to that established pursuant to Article 5.1. Even if Article 5.6 were relevant to the application of Article 5.7, the necessity of the measure would have to be judged by reference to the insufficiency of scientific evidence, and the reasonable period of time necessary. Furthermore, because the appropriate level of protection of the Community and the member States differs, even if they agreed on the science underlying the measure, they might still disagree on the measures to be taken.

*(i) Evaluation*

7.3377 The **Panel** recalls that it has already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under

Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the existing safeguard measures are also inconsistent with Article 5.6. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under Article 5.6.

*(ii) Overall conclusions*

7.3378 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article 5.6 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.6.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article 5.6 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.6.

(f) Consistency with Article 5.5 of the *SPS Agreement*

7.3379 The Panel next proceeds to address Canada's and Argentina's claims of inconsistency under Article 5.5 of the *SPS Agreement*.

7.3380 We recall that Article 5.5 provides in relevant part:

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade."

7.3381 **Canada** notes that its claim under Article 5.5 is presented in the alternative, that is in the event that the relevant member States' appropriate level of protection is that reflected in these member States' safeguard measures. Canada argues that the product-specific marketing bans meet all three elements that are required to establish a violation of Article 5.5. *First*, the European Communities has adopted different appropriate levels of sanitary and phytosanitary protection in "different situations" that are comparable.[2173] Canada notes that the European Communities has adopted different appropriate levels of sanitary and phytosantiary protection in at least three different situations: (i) EC-approved biotech products that are subject to the EC member State national measures; (ii) other EC-approved biotech products; and (iii) non-biotech varieties of the products in item. *Second*, those

[2173] Article 5.5 of the *SPS Agreement*. *See also*, Appellate Body Report, *EC – Hormones*, para. 214.

different appropriate levels of protection are "arbitrary or unjustifiable."[2174] *Third*, the measures embodying those differences, the product-specific marketing bans, result in "discrimination or a disguised restriction on international trade.

7.3382 **Argentina** argues that the bans on the safeguard measures by EC member States are inconsistent with Article 5.5 of the *SPS Agreement* since the three "elements" in Article 5.5 have been shown to have been violated cumulatively. Furthermore, the effect of the bans imposed by some member States on the biotechnology-producing countries is significant and adverse, inasmuch as it falls unfairly on imports. Argentina also argues, however, that in the interests of procedural economy a finding by the Panel that the relevant member State safeguard measures are inconsistent with Articles 5.1 and 2.2 will obviate the need for a further finding by the Panel that the safeguard measures are inconsistent with Article 5.5.

7.3383 The **European Communities** argues that Article 5.7 contains an express rule that effectively excludes Article 5.5. The European Communities considers that the member State measures to which Canada refers must be assessed by reference to Article 5.7 rather than Article 5.5. There is no basis for concluding that the member States have acted inconsistently with Article 5.5. Furthermore, the European Communities observes that consistency with Article 5.5 of the *SPS Agreement* should be evaluated in the context of the conduct of the European Communities. The European Communities has not behaved in an arbitrary manner or made unjustifiable distinctions such as those referred to in Article 5.5.

*(i) Evaluation*

7.3384 The **Panel** recalls that it has already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the European Communities acted inconsistently with its obligations under Article 5.5 in respect of the existing safeguard measures which embody particular levels of protection. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under Article 5.5.

*(ii) Overall conclusions*

7.3385 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article 5.5 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.5.

[2174] *Ibid.*

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article 5.5 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.5.

(g) Consistency with Article 2.2 of the *SPS Agreement*

7.3386 The Panel now addresses the Complaining Parties' claims of inconsistency under Article 2.2 of the *SPS Agreement*.

7.3387 We recall that Article 2.2 provides:

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

7.3388 The **United States** argues that a violation of Article 5.1 can be presumed to imply a violation of the more general provision of Article 2.2. The only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the European Communities' own scientific committees. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risks assessment, and are not "based on" a risk assessment, in violation of Article 5.1 and thus Article 2.2.

7.3389 **Canada** argues that a violation of Article 5.1 can be presumed to imply a violation of the more general provision of Article 2.2.[2175] Canada has already argued that the product-specific marketing bans are not "based on" risk assessments and are therefore inconsistent with Article 5.1. It can therefore be presumed that the product-specific marketing bans also violate the requirements of Article 2.2 that SPS measures be based on "scientific principles" and "not maintained without sufficient scientific evidence". Canada argues that since the product-specific marketing bans are inconsistent with Article 5.6 because they are more trade-restrictive than required to achieve the European Communities' appropriate level of protection, these measures must also be presumed to violate Article 2.2.

7.3390 **Argentina** argues that the inconsistency of the member State bans with Article 2 arises due to an inconsistency between these bans and Article 5. In addition, the lack of rational relationship between the member State safeguard measures and the scientific evidence renders these measures inconsistent with Article 2.2.[2176] The member State bans are not supported by scientific evidence. Furthermore, Article 2.2 requires that a measure be applied "only to the extent necessary," while also requires that it be based on "sufficient scientific evidence," whether it is to be implemented or to be maintained. Consequently, the member State bans also conflict with Article 2.2, and cannot be justified under the exception of Article 5.7.

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[2175] Canada refers to, *e.g.*, Appellate Body Report, *Australia – Salmon*, paras. 137-138.
[2176] Argentina refers to Appellate Body Report, *Japan – Agricultural Products*, para. 73.

7.3391 The **European Communities** argues that Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7.[2177] Article 5.7, rather than Article 2.2, is the provision to which Canada should have referred in order to properly understand the justification for the member State measures. "Necessity" can only be judged within a relevant time frame, taking into account any insufficiency in scientific evidence. Scientific principles include the principle that conclusions should be based on repeatable experiment, observation and the collection of data over time. Measures adopted on the basis of Article 5.7 are based on scientific principles, because they are based on the need to allow sufficient time for sufficient scientific evidence to be collected. There is therefore no basis for the Panel to conclude that the member State measures are inconsistent with Article 2.2 of the *SPS Agreement*.

7.3392 The **Panel** begins its examination by recalling that Article 2.2 contains three distinct requirements: (i) the requirement that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health, (ii) the requirement that SPS measures be based on scientific principles, and (iii) the requirement that SPS measures not be maintained without sufficient scientific evidence. It is appropriate to analyse separately the first requirement, on the one hand, and the second and third requirements, on the other hand.

*(i) First requirement of Article 2.2*

7.3393 Canada and Argentina allege that the safeguard measures they are challenging are inconsistent with the first requirement of Article 2.2.

7.3394 We recall that we have already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the existing safeguard measures are also inconsistent with the first requirement in Article 2.2. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under the first requirement in Article 2.2.

*(ii) Second and third requirements of Article 2.2*

7.3395 All three Complaining Parties allege that the safeguard measures they are challenging are inconsistent with the second and third requirements of Article 2.2.

7.3396 Here as well, we begin by recalling that we have already reached the conclusion that the safeguard measures challenged by the Complaining Parties are inconsistent with Article 5.1 in that they are not based on a risk assessment. In *Australia – Salmon*, the Appellate Body agreed with the panel in that case that in the event an SPS measure is not based on a risk assessment as required in Article 5.1, this measure can be presumed, more generally, not to be based on scientific principles or not to be maintained without sufficient scientific evidence within the meaning of Article 2.2. The Appellate Body concluded on that basis that "by maintaining an import prohibition on fresh, chilled or frozen ocean-caught Pacific salmon, in violation of Article 5.1, Australia has, by implication, also

[2177] The European Communities refers to Appellate Body Report, *EC – Hormones*, para. 104, in respect of Articles 3.1 and 3.3 of the *SPS Agreement.* The European Communities notes that Article 3.1 contains language essentially identical to that in Article 2.2.

acted inconsistently with Article 2.2 of the *SPS Agreement*".[2178] We consider that the same logic and presumption are applicable in the present case. Accordingly, we find that by maintaining the challenged safeguard measures inconsistently with Article 5.1, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2.

*(iii) Article 5.7*

7.3397 We have determined above that the relevant safeguard measures are inconsistent, by implication, with the second and third requirements in Article 2.2. Before coming to a final conclusion, however, we address whether the safeguard measures are consistent with the requirements of Article 5.7 of the *SPS Agreement*.

7.3398 We have found earlier that the safeguard measures at issue are not consistent with Article 5.7. This finding applies also to our analysis under Article 2.2, and so we confirm it here. Accordingly, there can be no doubt that the second and third requirements in Article 2.2 are applicable to the safeguard measures.[2179] This in turn confirms that these measures are contrary to Article 2.2, inasmuch as they are inconsistent, by implication, with the second and third requirements in Article 2.2.

*(iv) Overall conclusions*

7.3399 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that by applying, inconsistently with Article 5.1 of the *SPS Agreement*, the safeguard measures which the United States is challenging, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes as follows:

(a) It is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with the first requirement of Article 2.2 of the *SPS Agreement*. Accordingly, the Panel offers no findings with regard to the first requirement in Article 2.2 of the *SPS Agreement*.

(b) By applying, inconsistently with Article 5.1 of the *SPS Agreement*, the safeguard measures which Canada is challenging, the European Communities

[2178] Appellate Body Report, *Australia – Salmon*, paras. 137-138.

[2179] We recall that, earlier, we have left open whether Article 5.7 acts as a qualified exemption from the second requirement in Article 2.2. In view of our finding that none of the safeguard measures are consistent with Article 5.7, the issue is without practical significance for our analysis under Article 2.2, and so we do not address it further.

has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes as follows:

(a) It is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with the first requirement of Article 2.2 of the *SPS Agreement*. Accordingly, the Panel offers no findings with regard to the first requirement in Article 2.2 of the *SPS Agreement*.

(b) By applying, inconsistently with Article 5.1 of the *SPS Agreement*, the safeguard measures which Argentina is challenging, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(h) Consistency with Article 2.3 of the *SPS Agreement*

7.3400 The Panel finally addresses Canada's and Argentina's claims of inconsistency under Article 2.3 of the *SPS Agreement*.

7.3401 We recall that Article 2.3 provides:

> "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

7.3402 **Canada** notes that in *Australia-Salmon*, the Panel stated that a violation of Article 5.5 "can be presumed to imply a violation of the more general Article 2.3".[2180] In the case at hand, Canada has demonstrated that the EC member State national measures are inconsistent with the European Communities obligations under Article 5.5. By implication, therefore, these measures also violate Article 2.3.

7.3403 **Argentina** argues that as the member State bans have been shown to be inconsistent with Article 5.5, they also violate Article 2.3. Argentina also argues, however, that in the interests of procedural economy a finding by the Panel that the relevant member State safeguard measures are inconsistent with Articles 5.1 and 2.2 will obviate the need for a further finding by the Panel that the safeguard measures are inconsistent with Article 2.3.

7.3404 The **European Communities** argues that since the member State measures are not inconsistent with Article 5.5, they are not inconsistent with Article 2.3.

[2180] Canada refers to Panel Report, *Australia – Salmon*, para. 8.109. According to Canada, the Appellate Body upheld this statement. *See* Appellate Body Report, *Australia – Salmon*, para. 178.

*(i) Evaluation*

7.3405 The **Panel** recalls that it has already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the existing safeguard measures are also inconsistent with Article 2.3. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under Article 2.3.

*(ii) Overall conclusions*

7.3406 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article 2.3 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 2.3.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article 2.3 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 2.3.

**3. Analysis of the safeguard measures in the light of the *TBT Agreement***

7.3407 The Panel now turns to address Canada's and Argentina's claims of inconsistency under the *TBT Agreement*. The United States did not present claims under the *TBT Agreement*.

7.3408 **Canada** considers that the safeguard measures it is challenging are SPS measures and that, as such, they are not subject to the requirements of the *TBT Agreement*. Canada argues, however, that if the Panel decides that the safeguard measures at issue are not SPS measures, then Canada submits, in the alternative, that these measures are "technical regulations", as that term is defined in the *TBT Agreement*, and therefore subject to the requirements of that Agreement. Furthermore, in Canada's view, these measures are inconsistent with Article 2.1, Article 2.2, and Articles 2.9.1, 2.9.2 and 2.9.3 of the *TBT Agreement.*

7.3409 Furthermore, Canada states that to the extent that the Panel determines that parts of the measure at issue are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's TBT claims are to be considered cumulative rather than alternative, *vis-à-vis* its SPS claims.

7.3410 **Argentina** considers that the Panel should examine the measures Argentina is challenging under the *SPS Agreement*. However, if the Panel concludes that it should not examine these measures under the *SPS Agreement*, Argentina submits, in the alternative, that the safeguard measures at issue

are "technical regulations", as that term is defined in the *TBT Agreement*, and therefore subject to the requirements of that Agreement. Furthermore, in Argentina's view, by instituting bans on specific biotech products, these measures have violated Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*.

7.3411 The **European Communities** considers that, given the reasons on which the relevant safeguard measures are based, they fall in part within the scope of the *SPS Agreement* and in part outside the scope of the *SPS Agreement*. The European Communities does not agree, however, that the relevant safeguard measures are subject to the provisions of the *TBT Agreement*. In the European Communities' view, these measures are not "technical regulations" within the meaning of the *TBT Agreement*. For this and other reasons, the European Communities considers that these measures cannot be inconsistent with Article 2 of that Agreement.

(a) Evaluation

7.3412 The Panel begins its examination with Canada's claims. Canada has stated that if the Panel determines that parts of the relevant safeguard measures are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's claims under the *TBT Agreement* are to be considered cumulative rather than alternative. We have found, however, that each of the safeguard measures challenged by Canada constitutes in its entirety an "SPS measure" within the meaning of Annex A(1) of the *SPS Agreement* and hence falls to be assessed under that Agreement. In view of this finding and Article 1.5 of the *TBT Agreement*[2181], we do not consider that parts of the relevant safeguard measures are covered by the *TBT Agreement.* Consequently, we should treat Canada's claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement* as alternative claims. Since Canada's alternative claims are relevant only in the event that we decide that the relevant safeguard measures are not subject to the *SPS Agreement*, and since this is not what we have decided, we see no need to address Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement* further.

7.3413 Argentina's claims under the *TBT Agreement* are presented in the alternative, in the event the Panel finds that the relevant safeguard measures should not be examined under the *SPS Agreement*. We have found, however, that each of the safeguard measures challenged by Argentina should be assessed in the light of the *SPS Agreement*. In these circumstances, we see no need to address Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement* further.

(b) Overall conclusions

7.3414 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Articles 2.1, 2.2 or 2.9 of the *TBT Agreement*. Accordingly, the Panel offers no findings under Article 2.1, 2.2 or 2.9 of the *TBT Agreement.*

[2181] We recall that Article 1.5 states that the provisions of the *TBT Agreement* do not apply to SPS measures within the meaning of Annex A(1) of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Articles 2.1, 2.2 or 2.9 of the *TBT Agreement*. Accordingly, the Panel offers no findings under Article 2.1, 2.2 or 2.9 of the *TBT Agreement*.

## 4. Analysis of the safeguard measures in the light of the GATT 1994

7.3415 The Panel now turns to address the Complaining Parties' claims of inconsistency under the GATT 1994. Canada and Argentina have presented claims under Article III:4 of the GATT 1994. The United States and Canada have presented claims under Article XI:1 of the GATT 1994. The Panel first addresses the claims under Article III:4.

(a) Consistency with Article III:4 of the GATT 1994

7.3416 Article III:4 of the GATT 1994 provides in relevant part:

> "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

7.3417 **Canada** claims that Austria's safeguard measure on T25 maize, France's safeguard measures on Topas oilseed rape and MS1/RF1 oilseed rape (EC-161), and Italy's safeguard measure on MON810 maize, MON809 maize, Bt-11 (EC-163) and T25 maize fall within the scope of the GATT 1994 and are inconsistent with the European Communities' obligations under Article III:4.[2182]

7.3418 According to Canada, these four safeguard measures all are "laws, regulations or requirements laws, regulations or requirements affecting the internal sale, offering for sale, purchase, and distribution" of the biotech products concerned; the biotech products subject to these safeguard measures are "like" domestically produced non-biotech products in the light of four criteria put forth by the Appellate Body; and the imported biotech products concerned are accorded treatment less favourable than that accorded like non-biotech products of national origin. Therefore, Canada argues that the four safeguard measures constitute a violation of the European Communities' national treatment obligations under Article III:4.

7.3419 **Argentina** claims that Austria's safeguard measures on T25 maize, Bt-176 and MON810 maize, Germany's safeguard measure on Bt-176 maize, Italy's safeguard measure on MON810 maize, Bt-11 (EC-163) and T25 maize, and Luxembourg's safeguard measure on Bt-176 maize fall within the scope of the GATT 1994 and are inconsistent with the European Communities' obligations under Article III:4.

7.3420 According to Argentina, the biotech products subject to the safeguard measures and non-biotech agricultural products are "like" within the meaning of Article III:4 of the GATT 1994; the

[2182] Austria's measure on T25 maize, France's measures on Topas and MS1/RF1 oilseed rape, and Italy's measure on MON810, MON809, Bt-11 and T25 maize.

safeguard measures at issue are a "law, regulation or requirement" affecting "their [the products'] internal sale, offering for sale, purchase, transportation, distribution, or use"; and the treatment accorded to the imported (biotech) product is "less favourable" than accorded to the ("non-biotech") domestic product.

*(i) Evaluation*

7.3421 The **Panel** notes that Canada's claim under Article III:4 concerns four of the five safeguard measures challenged by Canada, namely, (i) Austria – T25 maize, (ii) France – MS1/RF1 oilseed rape (EC 161), (iii) France – Topas oilseed rape, and (iv) Italy – Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize. Argentina's claim under Article III:4 concerns all six safeguard measures challenged by Argentina.

7.3422 We recall that we have already reached the conclusion that the aforementioned safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 and, by implication, the second and third requirements in Article 2.2 of the *SPS Agreement*. In these circumstances, we see no need to examine, and offer additional findings on, whether the relevant safeguard measures are also inconsistent with Article III:4. Accordingly, as did previous panels in similar situations[2183], we exercise judicial economy with regard to Canada's and Argentina's claims under Article III:4.

*(ii) Overall conclusions*

7.3423 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article III:4 of the GATT 1994. Accordingly, the Panel offers no findings under Article III:4.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article III:4 of the GATT 1994. Accordingly, the Panel offers no findings under Article III:4.

(b) Consistency with Article XI:1 of the GATT 1994

7.3424 The Panel now turns to address the United States' and Canada's claim under Article XI:1 of the GATT 1994.

[2183] Panel Reports, *EC – Hormones (US)*, para. 8.272; *EC – Hormones (Canada)*, para. 8.275.

7.3425 Article XI:1 of the GATT 1994 provides:

> "No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party."

7.3426 The **United States** claims that the Greek safeguard measure on Topas oilseed rape violates Article XI:1 of the GATT 1994. According to the United States, the terms of the Greek measure make it unambiguously clear that the measure is an "import ban": "We prohibit the importing into the territory of Greece of seeds of the genetically modified rape-plant line bearing reference number C/UK/95/M5/1", and therefore, as an import ban, the Greek measure is a prima facie violation of Article XI:1.

7.3427 **Canada** claims that Greece's safeguard measure violates Article XI:1. According to Canada, as an import ban, the Greek ministerial decision constitutes an "other measure" provided for by Article XI of the GATT 1994, and, by the terms of that measure, Greece has both instituted and is maintaining a complete import prohibition on Topas oilseed rape seeds, contrary to Article XI:1.

*(i) Evaluation*

7.3428 The **Panel** notes that the United States' claim under Article XI:1 concerns one of the nine safeguard measures challenged by it, namely, Greece – Topas oilseed rape. Canada's claim under Article XI:1 is in respect of the same Greek safeguard measure.

7.3429 We recall that we have already reached the conclusion that the aforementioned safeguard measures being challenged by the United States and Canada, respectively, are inconsistent with Article 5.1 and, by implication, the second and third requirements in Article 2.2 of the *SPS Agreement*. In these circumstances, we see no need to examine, and offer additional findings on, whether the relevant safeguard measures are also inconsistent with Article XI:1. Accordingly, as did previous panels in similar situations[2184], we exercise judicial economy with regard to the United States' and Canada's claims under Article XI:1.

*(ii) Overall conclusions*

7.3430 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by the United States are inconsistent with Article XI:1 of the GATT 1994. Accordingly, the Panel offers no findings under Article XI:1.

[2184] Panel Reports, *EC – Hormones (Canada)*, para. 8.275; *Australia – Salmon*, para. 8.185; *Japan – Apples*, paras. 8.328-8.329.